UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 27, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 9 A.M. SESSION

(Pages 1876 - [[)

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I N D E X

EXAMINATION

EXHIBITS

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EXHIBITS

NUMBER	DESCRIPTION	PAGE
1680	McDonald Deposition, 07/29/2016 - Exhibit 21 - 7/13/2015 Warning Letter from the FDA regarding the 11/25/2014 Inspection of the C.R. Bard facility in NY and the 11/18/2014-1/5/2015 Inspection of the BPV facility in AZ	1925

10:01:31

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:29:46

THE COURT: Please be seated.

Morning, everybody.

MR. NORTH: Morning, Your Honor.

MR. LOPEZ: Morning.

THE COURT: Counsel, you saw the order I entered last night indicating my inclination to grant plaintiff one additional hour without subtracting it from defendants' time.

Mr. North, did you want to be heard on that issue?

MR. NORTH: If I could briefly, Your Honor.

Your Honor, the defendants certainly understand the Court's concern expressed in the order yesterday about any miscarriage of justice, but we are also concerned that a miscarriage of justice can go both ways in this circumstance.

We believe that changing the game rules at this point prejudices my client with any further adjustment. We have understood clearly the Court's instructions from the beginning. I think the instructions of the Court have been crystal clear. Repeatedly, at various conferences, hearings, *Daubert* hearings, the Court has time and time again discussed the time limitations, how they would work, what they would include, including closing.

08:30:04

08:30:26

08:30:42

08:31:00

08:31:02 I believe in the Court's order accepting the parties' stipulation to bifurcate the punitive damages, the Court once again reiterated that the time for the punitive phase would need to come out of the overall time limits.

08:31:15 Bard has made strategic choices in the pursuit of the defense of this case from the beginning, based on our understanding of the time limitations. We have done many things that we might not have done earlier if we knew that these time limitations were not going to be strictly enforced.

08:31:37 For example, Dr. McMeeking, the plaintiff's one and only true design expert. I cross-examined him for 27 minutes. That's a decision we probably would not have made, to curtail that cross-examination to that extent, if additional time had been available.

08:31:54 We made many, many cuts to depositions, probably to the benefit of the jury and everyone involved, but we made many cuts that we originally were going to go with because of our concern for time limitations.

And our determination to abide within those time

08:32:12 limitations affected strategic choices every step of the way in our handling of the plaintiff's case in chief and the handling of our case thus far.

There are at least two Ninth Circuit cases that I have seen; one the *General Signal Corporation versus MCI* case

08:32:30 at 66 F.3d 1500, and the *Amarel versus Connell* case, 102 F.3d

08:32:38 1494, both of which, in both cases, the Ninth Circuit has recognized that the fact that one party made strategic choices all along based upon time limitations imposed by the Court is a factor in determining whether the Court abused its
08:32:57 discretion in not affording additional time.

At the same time we've made these strategic choices, we respectfully suggest the plaintiffs have not. In addition to the repetitive questioning that the Court cited yesterday, there have been things that it's their choice, it's their
08:33:16 case, but that baffled us given time limitations.

They put Alex Tessmer, a Bard employee who was essentially just a tech test guy, who ran two tests on the Recovery filter, which is not the device in this case, and did the direct examination of him about those two tests for over
08:33:34 an hour and 45 minutes. And we believe the record is replete with other instances where they made strategic choices that I don't understand. It's not my choice to understand them. But they made those choices to use up their time.

We believe that the eleventh hour as we're coming
08:33:53 into the end of this trial to expand these time limitations is simply unfair, and we cannot roll back the clock and change the strategic choices the defendant made from the beginning based on the Court's time limitations.

So for that reason, we oppose the a extra hour.

08:34:15 THE COURT: All right. Thank you.

08:34:15 Mr. Lopez.

MR. LOPEZ: First, Your Honor, I think Mr. Tessmer's probably a good example of how difficult it was for me to get straight answers out of a witnesses that I had to ask him
08:34:27 multiple questions. We got five very important tests, I think was important to our case, that was early in the case.

The next -- Your Honor, when we first agreed, I said this yesterday, I found the transcript from October 5th, 2017, where it was agreed that we would have three weeks to try this
08:34:48 case, 66 hours total time for the cases. You asked if that was workable, and I said yes, it was.

And this is the Court: My thought would be with a three-week jury trial.

And we've always thought that should be the case.
08:35:06 We -- even with the FDA in this case, we could have appropriately addressed some of these issues that are coming in in the defense case.

You can't plan for everything during a trial Your Honor. When you look at your -- the motion, our FDA
08:35:19 exclusion motion, our *Cisson* motion, we can't -- we could not tell from your language how much of this additional evidence was coming in, other than the clearance issue. In other words, how these devices got cleared. It says you're leaving open the enforcement, some of the other activity that goes
08:35:42 beyond just the 510(k) clearance process.

08:35:44 The 510(k) clearance process is not that big a deal. I mean, it's just a document being submitted. That would be easily dealt with. We did not anticipate the kind of evidence that's coming into this case on FDA.

08:36:02 I don't think -- with due respect, Your Honor, I understand you think that we've wasted time. I don't think so. I mean, we've cut a lot of the stuff out of this case. You've heard me say that before. We've had depositions. We've got a number of exhibits we are not going to get into evidence that we need in this case because we had to take down some of the depositions that we designated. And I told you we sent three experts home that we're not calling in this case.

And, again, for the most part, the -- most of the difficulty we've had with time is trying to get the cooperation, I think, of some of their witnesses. It's amazing how cooperative they are under direct examination.

We did start nitpicking, Your Honor, here and there, about time. But the truth is if we did not efficiently use our time in the time we had, we're already paying that price. We've had to take down -- we've penalized ourselves by taking down evidence that we think is necessary for this case.

And we could not anticipate what was coming into evidence in the case and how much time to reserve until we actually started the defense case. And I'm just going to be honest, I -- in my wildest dreams, I didn't think that that

type of evidence was coming into this case. Certainly your order didn't indicate one way or the other.

I thought -- I mean, I understand the Court's reasoning, not that I agree with it, but for allowing FDA because of the Georgia law federal regulations. I mean, this could be about federal regulations and violations of federal regulations, but I -- the 403 objections, 402 objections we've made to the hearsay, the FDA's enforcement, lack of enforcement, all these communications going back between Bard and FDA, I mean, if anything, it's confusing to a jury. More concerning is it's misleading to a jury. And there's no way that we have the time to address that. We won't if you gave us another day or two.

All we're trying to do is finish this case. We have to restrict ourselves in cross-examining experts. We understand that. We don't want to find ourselves not being able to argue this case.

But I think it's important for the Court to know that when we first agreed to a three-week trial, it was 66 hours, and we were going to get 35 of that. And we could do that with 35 hours. But we can't do it with the time that we have left, which is going to be essentially 30 hours. Can't do it.

THE COURT: All right. Well, what I'm going to say on the record is I disagree with the description of what happened in that discussion of 66 hours. But that's not the

point to be decided.

I'm going to grant the plaintiff one additional hour for the reasons I stated in the order last night.

All right. The warning letter, FDA warning letter, I've read the briefs on both sides. Do you have additional points you want to make with respect to the FDA warning letter?

MS. REED ZAIC: Your Honor, I would just supplement the briefing with the testimony that came in yesterday after the briefs were due in the morning. We've heard about FDA and alerts and such. I think it goes to our 403 argument that we would be prejudiced if we cannot get this letter in.

In addition to the testimony we continue to hear that everything went to the FDA, there's FDA memos, you know, blessing everything that has happened that Bard has done. However, this letter says the exact opposite, and I think it would go to the weight of the evidence at this point.

THE COURT: All right.

MR. NORTH: Your Honor, we would essentially stand on our brief, but I would point out that we have made -- tried to be very careful not to open the door and make broad statements that the FDA has never taken a regulatory action or something of that nature and focused the questions about a recall, which that warning letter has nothing to do with.

We believe, for the reasons set forth in the brief,

that those individual complaints really have no relevance to the issues in this case. And you couple that with the fact that Bard's internal trending, and the testimony will be undisputed, Bard's internal trending of complaints includes everything. Whether it's reported to the FDA, how it's characterized as serious injury versus malfunction. And we believe, therefore, that this evidence is simply irrelevant and should be excluded under 402 and 403.

MR. LOPEZ: Your Honor, may I just -- I'm sorry. I thought you were done.

MS. REED ZAIC: Your Honor, they're saying that everything has gone to the FDA, but, again, it goes to the weight of the evidence that the FDA actually went back and realized that they weren't doing it right and it was in violation of a federal regulation.

Moreover, there was evidence yesterday that the FDA alerts -- I'm sorry, questioning that elicited testimony that these FDA alerts in 2010 went to all companies, and that leaves out a piece of the picture, which is that the FDA acted specifically to Bard.

THE COURT: All right. In my order on March 1st, I did not decide whether Section 3, Section 7, and Section 8 of the FDA letter should come in. I said that that was a decision that would be need to be made at trial once I understood the relevancy of the evidence that is contained in

08:41:32 the letter in light of the overall facts at trial.

My conclusion, now that I've heard the evidence, is that Section 3 of the warning letter is relevant to this case. I reach that conclusion for a few reasons:

08:41:50 The argument that was made by the defendants in the brief was largely a causation argument, that none of the complaints could have caused Ms. Booker's injuries because they were either after the implant or the doctors who removed the filter had no knowledge of those complaints.

08:42:07 I agree with that. I don't think it goes to causation. But I think the relevancy of Section 3 of the warning letter goes to a few other issues that have been addressed.

There has been much evidence before the jury about 08:42:23 the MAUDE database, about the data upon which Bard relied, upon reports to the FDA. There has been evidence about root cause analysis and when it was or was not done. There has been evidence about the fact that the FDA has not submitted questions, other than those that were identified in documents 08:42:46 that were put in evidence, has not taken recall action.

I believe the implication, if not the express argument to the jury, is that the FDA never took any action with respect to Bard.

And yet Section 3 of this letter does concern Bard's 08:43:05 handling and reporting of adverse events with respect to the

08:43:09 G2 filter in at least four different instances, as well as the adequacy of Bard's evaluation for root cause of the violations. Root cause is in Section 3A, the G2 filter is mentioned in Section 3B. 3C includes other filters which
08:43:29 apparently largely are unidentified, but which plaintiffs at least assert includes one G2 filter.

I think it's relevant in light of the information that's been presented to the jury. And, therefore, I'm going to permit the following portions of the G2 letter to be
08:43:45 presented:

Page 1, which is largely introductory information.

Page 4, starting with the heading "Quality System Regulation Violations of Tempe, Arizona Facility and Queensbury, New York Facility." That heading can be included,
08:44:07 as can the rest of the page, which is Section 3.

Page 5 through the end of the third paragraph. So it should not include the heading "Quality System Regulation Violations at Queensbury, New York," which is a different set of violations.

08:44:24 So that essentially leaves in all of Section 3.

And page -- the version of the exhibit I have actually has the page numbers out of order.

Page 10, beginning with the paragraph at the bottom that reads "Your firm should take prompt action to correct the
08:45:17 violations addressed in this letter," that paragraph at the

08:45:21 bottom can be left in. All of page 11 and all of Page 12, which is just the closing and the signatures, and all of page 13, which is simply the cc's.

So my ruling is that portion of the FDA warning
08:45:37 letter is relevant.

I do not believe Sections 7 and 8 are relevant. I previously indicated that. But, again, I don't think that's relevant because they relate to the Denali filter systems, which are not at issue in this case.

08:45:53 And I previously ruled in the order dated March 1st that this is not hearsay, that it's admissible under Rule 803(8).

So I will leave it to plaintiff to introduce the letter when you choose to do so. If there are other
08:46:10 objections, they can be made, but relevancy, 403, and hearsay, I'm ruling against defendant on their argument.

I'll tell you one of the thoughts, though, that I do have that we all ought to consider is I think I should give an instruction to the jury about redacted exhibits, because
08:46:30 there's going to be other redactions. And the essence of the instruction would be to tell them that there are portions of the exhibits that have been redacted, that those are based on my conclusions that the information redacted is not relevant or admissible for other reasons, the jury should disregard
08:46:47 those portions and not speculate as to what they might

08:48:44 just examples of all of your violations under 21 CFR 820.198(a)."

And we have meticulously gone through and submitted to the Court that these SOPs were in place during the time 08:48:56 that Ms. Booker had her filter.

THE COURT: Is it your argument that the standards and SOPs cited in paragraph 3A apply to more than components manufactured elsewhere?

MS. REED ZAIC: Since it's cited as simply an 08:49:26 example, I would have no idea because I have not deposed anyone who drafted this letter to Bard.

THE COURT: Is that what you're arguing, Mr. North, that these standards and SOPs only relate to components?

MR. NORTH: No, Your Honor, not at all. All I'm 08:49:48 talking about is in 3A, where it's talking specifically about the root cause, it's talking about complaints involving components made by other suppliers and the failure to figure out the root cause sufficiently. That specifically deals with the Denali filter and not the other filters.

08:50:08 THE COURT: Okay. I understand the argument. Because it is an example of what's in the first paragraph, I'm going to leave the designation that I indicated before as to what is admissible.

Jeff, would you remind me on that instruction. We'll 08:50:23 need to draft something up and include it.

08:50:26 All right. Plaintiff, do you have matters you want to raise this morning? We've get got about eight minutes.

MR. LOPEZ: I'm going to use those precious eight minutes off our clock, Your Honor, if you don't mind.

08:50:37 Exhibit 4327, the Court will recall, this was the exhibit where four pages at the back --

THE COURT: I remember the exhibit.

MR. LOPEZ: Okay. I'd like to make an offer of proof, Your Honor, on that, if I could right now as to why

08:50:52 it's a business record and should be included. It will take me two minutes with you, or maybe ten minutes with Mr. Carr.

May I?

THE COURT: Yeah.

MR. LOPEZ: Mr. Carr testified on December 19th,

08:51:08 2013, that complaints -- that their company collects complaints, it's put in a database and collected through their field assurance group, that many of these come in through their sales reps, and that the information is tracked by Bard relative to the Recovery and G2 devices.

08:51:25 And the information collected is maintained in what Bard refers to as a complaint file. And those complaint files are kept in electronic format -- database, rather, and summaries of those complaints can be downloaded and printed.

What you will see on this attachment, Your Honor, is

08:51:46 rep report, rep report, rep report, rep report. Those are the

sales reps that are reporting this pursuant to the business practices of Bard. These reps are agents of Bard that are reporting these.

We've cross-referenced the language that's in this against the complaint files, and the language, at least from the summary, is almost precisely the same. So I think we've now satisfied our requirement under the evidence code that these are statements, comments, made by an agent or employee of Bard and under the direction of Bard in their regular course of business.

And I'd like to --

THE COURT: You're mixing two hearsay exceptions there. One is business record, one is an admission of a party or statement of a party opponent through an agent. Which are you arguing?

MR. LOPEZ: Well, I can barely hear you, Judge.

THE COURT: Traci, would you see if this can be turned up.

My question is this: You've mixed two exceptions. One is the business records exception, and the other is the statement of a party opponent through an agent. They're different parts of the hearsay rules.

MR. LOPEZ: Right. I think they both apply. But this is clearly an agent on behalf of the company that's making these statements. It says rep report. We looked at

08:53:12 the backup complaint files for these. These are sales reps.

THE COURT: Well, but -- I understand the argument you're making, Mr. Lopez, but I can't apply that exception on the basis of your argument. There has to be evidence of what 08:53:25 you just described. That is, that the statements are statements from the reps that are the same as in their complaints. There hasn't been any evidence like that presented.

MR. LOPEZ: That's why I made the offer of proof.

08:53:39 THE COURT: Well, but the offer of proof has to be followed up with actual proof. How do you intend to present that evidence?

MR. LOPEZ: The evidence that these are sales reps?

THE COURT: No, the evidence that you made in your 08:53:51 offer has to actually come from that witness stand at some point. How do you intend to present that?

MR. LOPEZ: Well, he just testified at deposition that it's the sales reps --

THE COURT: I can't rely on his deposition. It has 08:54:03 to be trial testimony.

MR. LOPEZ: All right. I'll do it.

THE COURT: Are you saying you're going to elicit that from him?

MR. LOPEZ: Well, if he doesn't say it on the stand, 08:54:10 I'll read his deposition. I was hoping to short-circuit that

by showing the Court --

THE COURT: I can't short-circuit it on the basis of evidence that's not presented at trial. So it has to come in at trial.

MR. LOPEZ: I understand. It's just my effort to save a few minutes, Your Honor.

THE COURT: Well, I can't save time by disregarding the requirement that it has to be an evidentiary basis for the admission of the exhibit.

MR. LOPEZ: Very well. Thank you.

THE COURT: Well, before you leave, though, are you going to -- are you making the business record argument as well?

MR. LOPEZ: Well, yes. I mean --

THE COURT: What's the basis for satisfying 803(6) with respect to this?

MR. LOPEZ: Whether or not this is kept in the ordinary course of business?

THE COURT: And the other elements in 803(6). There's four of them.

And by the way, let me go ahead and say this now, I was going to say this before the next trial, when we get to business records, we are on both sides uniformly not touching all four of the bases in 803(6).

Now, when the defendant hasn't done that, there

usually hasn't been a hearsay objection, so I've admitted the exhibit. But if the plaintiff was objecting, I would sustain the objection until all four of the elements of 803(6) are met.

So please keep that in mind as we go forward, because all of those have to be met for 803(6) to apply.

Okay. Sorry for the interruption. Go ahead.

MR. LOPEZ: I'll give that my best shot, Your Honor. But I think under 801(d)(2)(C) and (D) and (A), all they have to do is establish that those statements were made by an agent of the company.

THE COURT: No, you have to do more than that.

MR. LOPEZ: Was made by the party in an individual representative capacity. That's (A). (C), was made by a person whom the party authorized to make a statement on the subject. (D), was made by the party's agent or employee on a matter within the scope of that relationship and while it existed.

THE COURT: Exactly. So --

MR. LOPEZ: Those are --

THE COURT: (C) and (D) are the relevant ones.

MR. LOPEZ: Right.

THE COURT: For (C), if it's going to be an agent, then there has to be evidence that the person was authorized to make the statement. And for (D), if it's an agent or

employee, there has to be evidence it was a matter within the scope of the employee or the agent relationship and while it existed.

MR. LOPEZ: Right. I get that. Except that I think -- I mean, I've read testimony that suggests that, and I'll do it with Mr. Carr.

THE COURT: Okay. I understand what you're going to argue. But I'll wait to hear that before I rule because I need the evidence.

MR. LOPEZ: All right.

THE COURT: Okay. Defendant --

MR. NORTH: Your Honor, I just have one additional charge right now, the jury instruction proposed that I was just going to leave with the Court.

THE COURT: Is that for this evening?

MR. NORTH: Yeah.

THE COURT: Why don't you hold onto it. I'm not going to have time to look at it during the day. Let's take it up tonight when we get to the jury instructions.

Anything else from plaintiff?

Mr. Condo?

MR. CONDO: Your Honor, the second witness, Dr. Feigal, is a clinical epidemiologist. He's going to talk about the types of studies reported in the medical literature. He would prefer to come down and use the white

board to list the types of studies, then return to the stand to explain all of the types of studies. I wanted to alert the Court to that and ask if that is permissible.

THE COURT: It is permissible. But what you'll need to do is bring the white board over to about where this projector is so I can stand over here and see what he's writing.

And whoever is the defense counsel that's going to cross him, you can step over into that side of the jury box so you can see it.

And he can list it. If you're going to have him testify about it after he lists it, let's get him back in the witness chair so the sound is good. But, yeah, you can do that. You can have him --

MR. CONDO: And by defense counsel, you're talking about plaintiff's counsel --

THE COURT: Yeah. Sorry. I meant plaintiff's counsel who is going to cross. If you want to come over into the end of the jury box to see what he's writing, that's fine.

MR. CONDO: Thank you, Your Honor.

THE COURT: Okay.

MS. MATARAZZO: One other issue. Defendants filed a brief this morning regarding the admissibility of the SIR guidelines. I don't know if Dr. Grassi's testifying today,

but that issue is going to come up --

THE COURT: I have not seen that brief.

MS. MATARAZZO: We've --

THE COURT: When are you calling Dr. Grassi?

MR. NORTH: Probably after lunch, Your Honor.

THE COURT: Okay. I don't know if I'll have time to read the brief before then.

MR. NORTH: I understand. I mean, we'll just argue it orally, if need be. But I just -- they may object. But I wanted to put that in the record.

MS. MATARAZZO: That's fine, Your Honor.

The other option would be to argue it, just come back five minutes early from lunch and address it. It's with regard to whether or not the SIR guidelines can come into evidence due to notice and knowledge to the medical community.

THE COURT: All right. Let's cross that bridge when we come to it.

Okay. Traci, let's bring in the jury.

(The jury entered the courtroom at 9:00.)

THE COURT: Please be seated.

Good morning, ladies and gentlemen. Thanks for being here this morning.

We're going to continue with the testimony of Mr. Carr.

Mr. North, you may proceed.

09:00:52 MR. NORTH: Thank you, Your Honor.

ROBERT M. CARR, JR.,

recalled as a witness herein, after having been previously sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N (CONTINUED)

BY MR. NORTH:

Q Good morning, Mr. Carr.

A Good morning.

Q I believe when we broke yesterday we were discussing Exhibit 503.

09:01:01 I'm sorry, 5303. And do you recall that?

A Yes.

Q And what is that again?

A It is the verification and validation report for the G2 filter.

09:01:23 MR. NORTH: Your Honor, I believe this was admitted yesterday or earlier. If we could display it to the jury.

THE COURT: 5303?

MR. NORTH: Yes.

09:01:34 THE COURT: You may.

MR. NORTH: And if we could turn to page 14.

BY MR. NORTH:

Q Down below this chart, what does this show regarding the migration testing performed on the G2?

09:02:03 A It shows the results of the test at 15 and 28-millimeters.

09:02:07 That's the diameter of the tube. And for the G2 filter.

Q And were these values for the G2 filter an improvement over what you had found with the Recovery filter?

A Yes, they are.

09:02:31 MR. NORTH: If we could turn to page 15.

And if we'd look at the chart at the bottom of the page.

BY MR. NORTH:

Q Does that compare the migration resistance values for the

09:02:50 Simon Nitinol, the G1A or G2, and the Recovery filter?

A Yes, it does.

Q And how did the G2 compare to the Recovery as far as the mean went?

A It's 15-millimeters less.

09:03:12 Q I'm sorry, the G2 compared to the Recovery filter as far as migration resistance under the mean, how did the G2 compare to the Recovery filter again?

A I'm sorry. It's 50 millimeters of mercury more.

Q Did the G2 reflect an improvement?

09:03:35 A Yes. Nearly double.

Q Let me ask you this: Did the G2 at any point fail migration testing?

A As we discussed before, the initial specification was to be equivalent to the SNF filter, and that specification was

09:04:01 changed to a more appropriate specification, which was to be

09:04:06 significantly improved over Recovery. And that's documented a little bit later, I believe.

MR. NORTH: Let's look at Page 21 of this exhibit, if we could.

09:04:18 BY MR. NORTH:

Q Under the conclusion, did the company explain how the standard was modified to compare the G2 to the Recovery filter?

A Yes.

09:04:37 Q And was this report actually submitted to the FDA?

A Yes.

MR. NORTH: If we could look at Exhibit 5252.

Your Honor, I believe this has already been admitted. If we could display it to the jury?

09:05:24 THE COURT: You may.

BY MR. NORTH:

Q We talked a little bit yesterday, I believe, about the competitive or comparison testing. Is this the report that -- of that testing that you performed, or the company performed?

09:05:39 A Yes.

MR. NORTH: If we could look at page 6.

BY MR. NORTH:

Q Does this demonstrate the various migration resistance that you found for the various products?

09:05:58 A Yes, it does.

09:06:01 Q Where on this chart can we find the G2?
A I don't see it.
Q Well, did we see earlier -- what did we see earlier that the mean value was for the G2 in migration resistance?
09:06:39 A I believe it was 106.
Q And how does that compare?
MR. NORTH: If we could look at the column that says "Mean."
THE WITNESS: Yes.
09:06:51 BY MR. NORTH:
Q How does 106 compare to most of the other filters?
A It's more than almost all.
Q And just so we know, do you know what some of these abbreviations over under the sample ID stand for?
09:07:09 A Yes.
Q Could you tell us what some of those are.
A The NMT is Recovery filters made at Nitinol Medical Technologies.
The RF are Recovery filters made at Glens Falls.
09:07:24 SF is Simon Nitinol.
GT is the Greenfield titanium filter.
GS is the Greenfield stainless steel.
VT is vena tech.
TP is the tulip.
09:07:43 O is the OptEase.

09:07:45 And T is the TrapEase. Two filters made by Cordis.
Q And those are competitive filters to the G2? Or would have been?
A Yes.
09:08:08 Q Did the company also, as a part of the development of the G2, perform a finite element analysis?
A Yes.
MR. NORTH: Let's turn to Exhibit 5037, if we could, please.
09:08:32 BY MR. NORTH:
Q Do you recognize what this document is?
A Yes.
Q And would you identify what it is.
A It's the process FMEA for the G2 filter.
09:08:44 Q Was this record made at or near the time it was dated by someone with knowledge from the company?
A I don't see a date. Sorry.
Q Well, do you recall when this would have been --
MR. NORTH: Let's go to the second page, if we
09:08:58 could.
No date there. Try the third.
BY MR. NORTH:
Q Do you recall approximately when this was prepared?
A Sometime around May 2005.
09:09:16 Q And would this report have been created by someone with

09:09:21 knowledge of the contents?
A Yes.
Q And would this record have been kept in the course of Bard's regularly conducted activities?
09:09:29 MR. LOPEZ: I'll agree to it, its admission.
MR. NORTH: We tender it, then, Your Honor.
THE COURT: All right. 5307 is admitted.
BY MR. NORTH:
Q And is this the report of the finite element analysis that
09:09:45 you discussed, or mentioned?
A No.
MR. NORTH: Well, let's go to the title page, if we could.
Let's turn to page 07, if we could.
09:10:03 BY MR. NORTH:
Q Do you know if Bard conducted this FEA itself, or did it work with a vendor to do so?
A I know the FEA was contracted out to a vendor.
Q And why did you contract out FEAs?
09:10:29 A Because of the skill set that they have to do it.
Q And did you --
MR. NORTH: I'm sorry, I see the source of confusion. This is supposed to be 5037 and this looks like it's 5307.
09:10:57 5037.

09:10:59 THE COURT: I think you had said 5307.
MR. NORTH: I'm sorry, Your Honor.
THE COURT: And so did you not intend to admit 5307?
MR. NORTH: I did not. I apologize.
09:11:09 THE COURT: So that exhibit won't be admitted.
Let's go to 5037.
BY MR. NORTH:
Q And what is this document, Mr. Carr? Can you tell?
A This is the effects of changes to the Recovery filter and
09:11:30 the femoral delivery system on filter stresses based on FEA
analysis.
Q And was this prepared by -- well, is this an approval form
signed off on by your team?
A Yes.
09:11:45 MR. NORTH: Your Honor, at this time we tender 5037.
MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 5037 admitted.)
MR. NORTH: Now, if we could turn to page 4 of this
09:11:58 exhibit.
And could we display this to the jury, Your Honor?
THE COURT: Yes.
BY MR. NORTH:
Q Does this describe the test rationale?
09:12:11 A Yes.

09:12:12 Q And what was the purpose of this test? This finite element analysis that Bard had conducted on the G2?
A To evaluate the stresses in both the loaded and the deployed condition of the filter. So meaning when it's in the
09:12:27 delivery system, and then when it's in a vessel.
Q Why did you want to do this in both configurations?
A Because the filter is stored in the delivery system from the time it's made to the time it's used, so you have to test those conditions, and then in the as-used condition also.
09:12:57 Q And would this finite element analysis have assessed the worst case scenario for the filter?
A Yes.
MR. NORTH: If we could turn to page 5.
BY MR. NORTH:
09:13:08 Q What was the conclusion of this finite element analysis performed on the G2?
A That the modified filter showed substantially lower peak stresses compared to the original design, up to 90 percent lower, with an exception being the legs, as the legs of the G2
09:13:28 filter are wider than the legs of the Recovery filter, so you would expect a little more stress there. However, the increase is minimal and the resulting deformation is well within the Nitinol's elastic range.
Q Would that stress found on the legs have affected the
09:13:53 fracture resistance of the filter?

09:13:56 A No.
Q Are the tests contained in the design verification and validation report the only bench test that Bard performed on the G2 filter?
09:14:17 A No.
MR. NORTH: Let me bring up 5949, if we could.
BY MR. NORTH:
Q Do you recognize this document?
A Yes.
09:14:40 Q And what is this?
A It's a clot trapping efficiency report.
Q And what was the purpose of this test?
A To measure the clot trapping of the G2 filter, I believe, in various configurations.
09:14:57 Q And when was this test conducted?
A I would guess in May of '06.
Q And what was the purpose of conducting this test after Bard had already started selling the G2 filter?
A To evaluate, again, the ability of the filter to trap
09:15:16 clots in different orientations, not just straight orientation.
Q Did this test try to compare the G2 filter clot trapping ability to that of the Greenfield filter?
A Yes.
09:15:32 Q And why did you choose the Greenfield filter as a frame of

09:15:37 reference for comparison?
A Because it was the filter that we have always compared to historically for clot trapping. First Recovery, and then G2.
Q Well, why did you choose that to compare for clot
09:15:52 trapping?
A It was the gold standard at the time.
MR. NORTH: Your Honor, at this time we would tender 5949.
MR. LOPEZ: No objection, Your Honor.
09:16:01 THE COURT: Admitted.
(Exhibit 5949 admitted.)
BY MR. NORTH:
Q After -- in the development of a product such as the G2, after the company completes the design verification and
09:16:16 validation testing, what is the next step?
A We have a design review to review all of the data.
Q And what does a design review consist of as a procedure or process?
A As I outlined yesterday in those processes of product
09:16:38 development, it is a review by, typically, senior people to walk through everything and make sure that everything was done to our quality documentation.
MR. NORTH: If we could bring up 5315, please.
BY MR. NORTH:
09:17:00 Q Do you recognize this document?

09:17:02 A Yes.
Q And what is that?
A It's the design review for the G2 filter femoral delivery system.
09:17:11 MR. NORTH: If we could look at page 3, please.
BY MR. NORTH:
Q Does this indicate when the design review took place?
A Yes. February 22nd, 2005.
MR. NORTH: Your Honor, at this time we would tender 5315.
09:17:25 MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit 5315 admitted.)
MR. NORTH: If we could display this page, Your Honor?
09:17:37 THE COURT: You may.
BY MR. NORTH:
Q Does this show who all attended the design review for the G2?
09:17:47 A I don't know if it shows all the attendees, but it shows the team members and reviewers.
Q Do you recall whether you attended that meeting?
A I don't recall offhand, no.
MR. NORTH: If we could turn to page 4, please.

09:18:05 BY MR. NORTH:
Q What is the -- is identified as the objective of this meeting?
A The objective is to critique the final design with respect
09:18:19 to the design requirements and specifications. The review team will determine if the G2, G1A, Recovery, is suitable to move into Phase III or process qualification.
Q And what did the design review team, what do they typically review as a part of this analysis?
09:18:40 A I believe if you take away the highlight, all of the documentation there in the agenda. All of the documentation that's required there.
Q Do they -- does the design review team look at all of the testing that has been done to develop the product?
09:19:01 A Yes.
MR. NORTH: If we could turn to Page 21, please.
BY MR. NORTH:
Q What were the conclusions of the design team? Design review team?
09:19:13 A That the filter demonstrated superior performance in fatigue resistance to the Recovery. The filter demonstrated acceptable performance in all tests, except for the migration resistance we talked about before. And that the G1A demonstrated superior performance in migration resistance
09:19:33 compared to Recovery.

09:19:37 Q Is this Phase II the only design review you conducted with regard to G2?

A No.

MR. NORTH: Let's bring up 5316, if we could.

09:19:53 BY MR. NORTH:

Q Are you familiar with this document?

A Yes.

Q And what's -- what's the title?

A Phase III Design Review for the G2 Recovery Femoral Delivery System.

09:20:06 Q And what would be the distinction between this design review and the one that we just talked about?

A I believe this one goes over the process of documentation.

MR. NORTH: If we could look at the 6th page.

09:20:22 Page 6.

BY MR. NORTH:

Q Does this indicate who -- what date this took place?

A March 28th, 2005.

Q And does it list the people that attended?

09:20:36 A Again, there might have been other attendees, but it lists the project team and the design review team, yes.

Q And are you a part of that -- listed as part of that project team?

A I am.

09:20:46 MR. NORTH: Your Honor, at this time we would tender

09:20:48 5316.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5316 admitted.)

09:20:53 MR. NORTH: If we could display, Your Honor?

THE COURT: You may.

MR. NORTH: If we could turn to page 7, please.

BY MR. NORTH:

Q And what was the objective of this March meeting?

09:21:14 A To review all the testing and documentation, to ensure compliance to design specifications, and to ensure that the device will perform in a reliable, safe, and effective manner prior to full market release. And the review team will also determine if the system is suitable to move to Phase IV, 09:21:35 market release.

MR. NORTH: If we could go to Page 9, please.

Let's back up to 8, if we can.

BY MR. NORTH:

Q What were the conclusions of this particular design 09:22:06 review? Do you know?

A That we could move forward.

Q And as a part of this design review, did you validate the processes?

A Yes.

09:22:21 Q And what does that mean, to validate the processes for the

development of the G2?
A To ensure that the instructions and how you make the filter is how it was intended.
Q As part of your work with filters over the last 20 years or so, Mr. Carr, have you spent a lot of time with doctors and visiting hospitals?
A Yes.
Q And have you had many discussions with the doctors regarding their use of filters?
A Yes.
Q And as a part of your research and development and experience with filters, have you gained an appreciation of the types of patients who typically receive a permanent filter?
A Yes.
Q And what are the attributes of patients that doctors, in your experience, generally utilize permanent filters with?
MR. LOPEZ: Foundation. Speculation.
THE COURT: Overruled.
THE WITNESS: Typically it's in older patients whose life expectancy is not very long, and they would get a permanent filter. Or, stated better, they would not need an optional filter because they would probably never have it removed. Or they have a permanent need for a vena cava filter.

09:24:00 BY MR. NORTH:
Q Since the advent of retrievable filters in the early 2000s, has Bard seen the sales of its permanent filter, Simon Nitinol, decline?
09:24:13 A Yes, it declined year over year.
Q And as someone in the company who's worked closely with these filters in developing them, did you see reasons or have -- were you able to identify reasons why that was happening?
09:24:32 A Again, optional filters are permanent --
MR. LOPEZ: He just asked him if -- because I might have an objection to the narrative he's about to give. So I object. He's going beyond the scope of the question.
THE COURT: Reask the question, would you, please.
09:24:51 BY MR. NORTH:
Q With your work in filters, Mr. Carr, and the development of them, talking to doctors, visiting hospitals, what is your impression as to why the sales of the Simon Nitinol has declined?
09:25:12 MR. LOPEZ: Your Honor, objection. 802. Foundation. Speculation.
THE COURT: Overruled.
THE WITNESS: With the advent of optional filters, they are permanent filters also. So the number or the people
09:25:29 who received a permanent filter was going down, and new

09:25:35 technology has come along over time. The SNF is an old device. And so with the option of being able to remove a filter, that's what most people choose.

BY MR. NORTH:

09:25:50 Q Have you, in your work, identified certain characteristics of the Simon Nitinol filter that make it less desirable, besides the fact that it's only a permanent filter?

MR. LOPEZ: Again, Your Honor, lacks foundation. Seems to be asking for an opinion of an expert.

09:26:09 THE COURT: Overruled.

THE WITNESS: Yes. Many people don't like how the Simon Nitinol filter deploys. It is a very long device inside the tube and inside the delivery system, and when it's deployed into the vena cava, some people are not very

09:26:25 accurate with how it forms and -- which is very important to a lot of people is to be able to place the filter where they want it to go. So that's probably the biggest reason.

BY MR. NORTH:

Q Mr. Carr, are you aware of any IVC filter on the market

09:26:45 today that does not have reports of filter fracture?

A No.

Q Are you aware of any IVC filter on the market today that does not have reports of filter migration?

A No.

09:26:55 Q Are you aware of any IVC filter on the market today that

09:26:58 does not have reports of filter perforation?
A No.
Q And are you aware of any IVC filter on the market today that does not have reports of filter tilt?
09:27:08 A Probably not the Bird's Nest, which was a very old device and probably couldn't tilt.
Q Other than that one, are you aware of any?
A No.
Q If the G2 has had reports of fracture, as we've heard
09:27:25 during this trial, why did Bard continue to market the filter?
A Because of the benefit that it provides patients.
Q What is your understanding, as someone involved in the development of filters, regarding the typical clinical consequences of a fracture?
09:27:46 A The vast majority of cases, they are asymptomatic.
Q Mr. Carr, at any point in time in the development of the G2 filter, did Bard rush the filter to market or otherwise compromise the design and development process?
A No.
09:28:14 Q And do you believe yourself that the G2 is and was reasonably safe?
A Absolutely.
MR. NORTH: Thank you, sir. That's all the questions I have.
09:28:25 THE COURT: Cross-examination.

MR. LOPEZ: Yes, Your Honor. Thank you.

C R O S S - E X A M I N A T I O N

BY MR. LOPEZ:

Q Morning.

A Good morning.

Q Mr. Carr, you talked a lot about testing, and I want to make sure that the evidence in this case is clear.

You have previously testified that it's important for people to know that the FDA does not test; correct?

A I don't recall that.

MR. LOPEZ: Greg, could you please put up the June 6th, 2017, deposition of Mr. Carr, page 51, lines 12 through 17.

BY MR. LOPEZ:

Q Remember your deposition was taken in June of last year?

Sir?

A Yes.

Q You were asked, "So your testimony would be that Bard fully responded to the FDA but that the FDA was not satisfied with Bard's response?"

Your answer was, and I quote, "And I think it's important to know that the FDA doesn't -- doesn't test -- doesn't tell you how to test, they just tell you you need to test."

Remember that testimony?

09:29:42 A Yes.
Q And isn't it also your testimony that with respect to any IVC filter, that the FDA conducted none of its own testing on these filters?
09:29:54 A I don't believe the FDA's conducted testing on filters, no.
Q And so you get to choose what tests you do, and you send those results to FDA; correct?
A No. There's a guidance document.
09:30:06 Q I understand. But you still choose what test you do on these devices.
A Yes. But if you didn't fulfill the guidance, you wouldn't receive approval.
Q Now, you were asked a question about ten or 15 minutes
09:30:22 ago: Did the G2 ever fail migration testing in any of the tests you performed? Do you recall that?
A I do.
Q And the truth is, sir, that the G2 did fail migration testing once they were implanted in humans. True?
09:30:42 A No.
Q So these devices acted exactly the way you expected and intended them to happen once they were implanted in human beings?
A Yes. Migration is a known complication of all vena cava
09:30:59 filters, including G2.

09:31:01 Q So you expected 18 people to die from migrations when you marketed the Recovery filter?
A No.
Q Did you expect five people to die when you marketed the
09:31:14 Recovery filter from migrations?
A No.
Q Did you expect that the G2 filter would have had an unacceptable risk of caudal migration within the first three or four months that it was on the market?
09:31:29 A No.
Q The truth is, when the testing of these devices, including the G2, let's just say the G2, once you started testing these devices in human beings in the open market, it was failing the migration testing that you would have expected in human
09:31:53 beings. True?
A No. And we don't test migration resistance in human beings.
Q Well, you're not supposed to; correct?
A And we don't.
09:32:03 Q And when you first started marketing the G2, you had no clue how the G2 device was going to respond to -- within human beings. True?
A Absolutely not.
Q You knew that it -- you were going to have those caudal
09:32:21 migration problems, those perforation problems, those tilting

problems, those fracture problems that were reported to you in the early four to five months it was on the market? Did you know that was going to happen?

A Again --

Q Sir, did you know that was going to happen? That data?

MR. NORTH: Your Honor, I'm sorry.

THE COURT: Please let him answer the question, Mr. Lopez.

THE WITNESS: Again, all filters have known complications of which each of those that you listed are known. So, yes, we knew they were going to happen.

BY MR. LOPEZ:

Q All those things that were reported to you that caused Dr. Ciavarella to say, why are we using the G2 when we have the SNF, you expected all that to happen?

A Again --

Q Sir, that -- did you expect all that to happen that caused him to say, why are we using the G2 when we have the SNF that has virtually no safety problems?

A Again, yes. Those are all known complications of vena cava filters.

Q And you expected the results that you got in the EVEREST study when you first started marketing the device?

A I don't understand. Sorry.

Q The results in the EVEREST study, the tilting, the

09:33:26 migrations, the fractures, the perforations, the difficulty to remove these devices because they were embedded in the wall of the vena cava, did you expect that?

A Yes. And I believe they're known complications written in

09:33:39 the protocol of the clinical trial.

Q And did you tell doctors about that expectation, that the G2 filter was willing to behave the way it was reported to this company in the first four or five months it was on the market?

09:33:52 A Yes. The IFU instructs physicians of all of those known complications.

Q And you told doctors and patients about the results of the EVEREST study -- you did not tell doctors and patients about the results of the EVEREST study until sometime after

09:34:11 Ms. Booker got her device, her G2 device. True?

A Yes.

MR. LOPEZ: Could we pull up 1680, please.

Show it to the witness.

Please.

09:34:40 BY MR. LOPEZ:

Q Sir --

THE COURT: Hold on just a minute. What's the number?

MR. LOPEZ: 1680.

09:34:50 THE COURT: We're checking to confirm it's in

09:34:51 evidence.

MS. REED ZAIC: It's not. It's the redacted issue we dealt with this morning, Your Honor.

THE COURT: Oh. Okay.

09:35:01 BY MR. LOPEZ:

Q Sir, do you recall your company getting a warning letter from the Department of Health and Human Services dated July 13, 2015?

A Yes.

09:35:13 Q Were you involved in the activities that happened at Bard once this letter was received?

A No, I was not.

Q Do you recognize this, though, as the warning letter that you received? The company received?

09:35:29 A I don't know that I've ever seen the warning letter, but it certainly looks like a warning letter to Tim Ring, yes.

Q And Tim Ring is the chairman and chief executive officer of C.R. Bard?

A Yes.

09:35:43 Q And could you verify for us, please, if you look at page 11 of this Bates -- yeah, Bates page 11, 5715, that that is a signature of a director from the Los Angeles district of the FDA.

A It appears to be, yes.

09:36:06 MR. LOPEZ: Your Honor, at this time, subject to the

redactions that we discussed, I'd like to offer 1680 into evidence.

THE COURT: Other than the objections we've addressed, are there any others from defendants?

MR. NORTH: Your Honor, I would object to -- with this witness under 602. He hasn't been able to identify this.

THE COURT: All right. I'm going to overrule it. I believe this is self-authenticating under Rule 901 and 902.

Exhibit 1680 is admitted in its redacted form.

(Exhibit 1680 admitted.)

MR. LOPEZ: Thank you, Your Honor.

You can take that down now, Greg.

BY MR. LOPEZ:

Q Sir, your company maintains what are known as complaint files; right?

A Yes.

Q And those complaint files are collected by field assurance representatives?

A Yes.

Q And they can also be sent in by doctors and other folks; right? There's no restriction.

A Anyone can complain.

Q In fact, you instruct your sales reps if a doctor registers a complaint to them that they -- that complaint gets

09:37:08 reported to the company; correct?
A Yes.
Q And that information is tracked in a database that Bard maintains that includes both the Recovery and the G2 devices?
09:37:22 A Yes.
Q And those are kept in electronic database?
A Yes.
Q And those are kept in the ordinary course of business; right?
09:37:34 A Yes.
Q And the sales reps are authorized and in fact they're instructed to make sure they report any complaints that happen in the field; correct?
MR. NORTH: Your Honor, I'm going to object. This
09:37:43 is beyond the scope of direct testimony.
MR. LOPEZ: Your Honor --
THE COURT: Hold on just a minute.
Overruled.
BY MR. LOPEZ:
09:37:58 Q True, sir?
A Yes.
Q And, in fact, when you have a complaint file, you indicate who it was that reported it. True?
A I believe so.
09:38:12 Q And if it was reported by a sales rep, you put on the

09:38:15 complaint file a rep report or a sales rep report; correct?
A I don't do anything. I don't deal --
Q That's --
A -- with complaint forms.
09:38:24 Q I'm sorry, I didn't mean to interrupt.
But when you look at these complaint files, if a sales rep reports it, you'll see something like rep reported, that type of information?
A Probably.
09:38:37 Q Okay.
MR. LOPEZ: Your Honor, I'd like to now show the witness 4327. However, I want it to include the last four pages of that original exhibit.
THE COURT: That's fine. You can show it to the
09:38:51 witness.
MR. LOPEZ: Yes. Just show it to the witness, please.
Greg, that would be Page 8.
BY MR. LOPEZ:
09:39:03 Q Do you see that, sir?
A I do.
Q Now, you see on this chart rep report, rep report, rep report, rep report, rep report, all up and down that first page?
09:39:19 A Yes.

09:39:20 Q And these are complaints from the field; correct?
A Yes.
Q When it says "rep report," that means a sales representative who's an agent or employee of Bard reported
09:39:31 these events to Bard; correct?
A Probably.
Q And if you go to the next page, I think you'll see other areas where it says rep report and rep report.
Right?
09:39:50 A Yes.
Q And you've seen summaries like this before from the complaint files, have you not, that are indicated here on this Exhibit 4327?
A I saw this table the other day when you showed it to me.
09:40:12 MR. LOPEZ: Your Honor, at this time I'd like to move in the remaining four pages of 4327.
MR. NORTH: Same objection, Your Honor. Hearsay within hearsay.
THE COURT: All right. Let's address this for a
09:40:22 minute at sidebar.
If you want to stand up, ladies and gentlemen, feel free.
(Bench conference as follows:)
MR. LOPEZ: Your Honor --
09:41:37 THE COURT: That can't help me unless it's in

09:41:39 evidence.

MR. LOPEZ: Okay.

THE COURT: Mr. North, the question I have is, is why you think 801(d)(2)(C) has not been satisfied by

09:41:52 Mr. Carr's testimony?

MR. NORTH: Because I believe that the mere fact that it says "rep report" is just the tip of the iceberg of the layers of this hearsay. No selling representative knows -- may I look at this one second, Your Honor?

09:42:09 THE COURT: Yes, you can.

MR. NORTH: -- details such as on follow-up imaging the filter was found to have dropped, vertebral bodies link, doctor reported that one hook -- these may be coming from the sales rep and -- on some level, but there are many layers of

09:42:28 hearsay beneath.

The sales rep was not in the operating room. The sales rep is hearing about this from the doctor, is hearing about this from the physician, and so this is just a statement where the sales rep is reporting hearsay. It's not a

09:42:42 statement that he has personal knowledge of. And I don't think it would qualify under that -- not exception, but -- to fail to be identified as hearsay there because of that.

THE COURT: Well, the one you pointed out, which is the fourth bullet on Page 8 of Exhibit 4327, actually that

09:43:04 begins "marketing manager reported."

09:43:08 MR. LOPEZ: I can ask him that question too.
THE COURT: But it specifically says "doctor reported that one hook was in a vein." That is clearly stating what the doctor said.
09:43:18 MR. LOPEZ: And this is clearly notice to the company.
THE COURT: Well, but there's a hearsay issue. How is that not -- the doctor's statement in that sentence not hearsay?
09:43:27 MR. LOPEZ: Well, it is. But there's -- I mean, it's obviously -- but this is -- this is him reporting to the company, Your Honor.
THE COURT: What a doctor said.
MR. LOPEZ: Well, okay.
09:43:39 THE COURT: What the doctor said is hearsay.
MR. LOPEZ: Isn't it also notice to the company? This is --
THE COURT: There's no notice exception to the hearsay rule.
09:43:47 MR. LOPEZ: There's a notice exception to the hearsay rule.
THE COURT: No, there isn't.
MR. LOPEZ: Well, then, we won't offer it for the truth, and then it goes to their state of mind and
09:43:54 information they had when they were monitoring this device.

09:43:57 THE COURT: What's your response on that?

I mean, that would be accompanied by an instruction that they're not to take this information for the truth of what is said, but simply as notice to the company of what was
09:44:15 purportedly said.

MR. LOPEZ: I can live with that.

MR. NORTH: Your Honor, he just spent the last ten minutes answering his questions saying there's notice to the company of all these sorts of complications occurring. He's
09:44:26 trying to get this in for the truth of the matter asserted because he wants to get in that there's notice to the company of these specific details of events. I mean, he wants -- he wants evidence that the company -- well, that these events with these particular specifics occurred. He's already got
09:44:45 plenty of evidence of notice of complications occurring.

THE COURT: Well, but he can put in more evidence of notice.

MR. NORTH: That's true.

THE COURT: I'm not understanding that objection.

09:44:56 MR. NORTH: I think my point is that I don't believe that's why he's putting it in. He's putting it in to get the truth of these events before the jury.

THE COURT: Well, let me ask you this question, Mr. Lopez: Let's say you're in closing and you put this
09:45:08 exhibit on the screen, what are you going to argue from the

09:45:12 statements in this exhibit?

MR. LOPEZ: Whether the company had notice of the reports from their sales reps about what was happening with the device in the market.

09:45:25 THE COURT: Well --

MR. LOPEZ: It --

THE COURT: Hold on just a minute.

Here's the issue. Doesn't that, for the jury to say, okay, the company had notice that the filter was tilted 09:45:35 90 degrees against the caval wall, have to assume the filter was tilted 90 degrees against the caval wall? For the jury to attach significance to that, don't they have to assume the filter was actually that filter?

MR. LOPEZ: What they have to assume is what did the 09:45:53 company do in reaction, in response to that.

THE COURT: Why did the company have to do anything if it wasn't true?

MR. LOPEZ: Well, that -- well, one of the issues is they need to find out.

09:46:01 THE COURT: But it seems to me your argument implicitly asserts that these things really happened. That's why I'm wrestling with it's not offered for the truth of the matter asserted.

MR. LOPEZ: Alls I heard, all we heard in this case 09:46:12 is fracture rates. Those are all reports -- everything in

this case with respect to --

THE COURT: Let's focus on hearsay.

MR. LOPEZ: I know, but --

THE COURT: That's the issue.

MR. LOPEZ: Everything that relates to what -- this is -- clearly goes to the company's state of mind and the notice to them about --

THE COURT: I understand that, and I agree that it does. But it seems to me the only significance is if it's true information, if these filters were tilting in this way, were fracturing in this way. That's what I'm wrestling with.

MR. LOPEZ: Why can't I cross-examine someone and say, by the way, your sales rep reports that there was a device that went into someone's heart, or that a piece of the device went into someone's heart, what did you do to investigate that to see if it was true? Why can't -- I can't ask that question?

THE COURT: Well, you're not wanting to ask a question, you're wanting to put a document in evidence. There's a difference.

MR. LOPEZ: Okay. But it still doesn't stop me from finding out what kind of investigations --

THE COURT: You can ask him questions about investigations, and if there's an objection, I'll rule on it. What you want to do is put these statements in evidence.

09:47:19 MR. LOPEZ: Well, Your Honor, I would like to file a brief on this, obviously, because there's other cases where these come in to evidence as exception to the hearsay rule.

THE COURT: Well, let's do this: I think you've
09:47:32 laid the foundation. If you want to lay more, such as a marketing manager, you can go ahead and do that now.

And I'd like to see the cases. I'd like to consider that argument.

MR. NORTH: I think we have some, too, Your Honor.

09:47:45 MR. LOPEZ: Pardon me?

MR. NORTH: We have some cases too.

THE COURT: Okay. So I'm -- just for the record, I'm not going to admit it at this point, but it's subject to my hearing these additional legal arguments.

09:47:54 (Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. LOPEZ:

Q Sir, marketing managers can also report these adverse events, too, or regional managers. Anyone out in the sales
09:48:23 force that's with doctors. True?

A Anyone in the company can report any of them.

MR. LOPEZ: Those are all the questions I have at this time, Your Honor.

THE COURT: All right. Redirect?

09:48:37 MR. NORTH: Nothing further, Your Honor.

09:48:38 THE COURT: All right. Thank you, Mr. Carr. You can step down.

MR. LOPEZ: Your Honor, subject to our discussions, I'd like to move into evidence, I think it was 4327, but that 09:49:11 includes the -- to include the last four pages.

THE COURT: All right. That motion's been made. As indicated, we're going to discuss that later.

And that was 4327. Is that --

MR. LOPEZ: 4327.

09:49:27 MR. CONDO: Your Honor, we would call Dr. David Feigal.

THE COURTROOM DEPUTY: Dr. Feigal, if you'll please come forward and stand right here and raise your right hand, sir.

09:49:39 **DAVID W. FEIGAL, MD,**

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. CONDO:

09:49:57 Q Good morning, Doctor. Would you please introduce yourself and tell the ladies and gentlemen of the jury where you live.

A My name is David William Feigal, Junior, and I live in Thousand Oaks, California.

Q And what is your profession, sir?

09:50:31 A I'm a physician. I'm also an epidemiologist, and I have

09:50:37 spent the majority of my career, some 30, 35 years, involved in developing medical products.

Q And what is an epidemiologist?

A Epidemiology is the study of the patterns of diseases in

09:50:52 populations. So the word comes from epidemic, but it is broader than just studying infections. But that was the original use it was put towards. So it's a -- it's a field of study that looks at how things occur and what kinds of people and what are risk factors that explain the occurrences.

09:51:17 Q And is a clinical epidemiologist someone who is trained both in clinical medicine and in the research tools of epidemiology?

A Yes, that's right. So as a physician epidemiologist, I look at the epidemiology of the safety of medical products,

09:51:33 the patterns of diseases. I've done studies of specific diseases and conditions over my career.

Q And in this case what were you asked to do?

A I was asked to look to see if the studies that were in the medical literature could establish the rates and the extent of

09:51:55 the adverse events that were occurring with Bard filters and, to an extent, other filters as well.

Q And when you talk about studies referenced in medical literature, are you talking about peer-reviewed studies and medical publications?

09:52:11 A Yes, I am.

09:52:12 Q And have you formed an expert opinion on that subject on which you were asked to do?
A Yes.
Q And are all of your opinions formed to a reasonable degree
09:52:21 of scientific certainty?
A Yes, they are.
Q What education and training do you have in the field of clinical epidemiology?
A Well, I began my training as a -- at a medical school at
09:52:33 Stanford University. I did a residency in internal medicine at the University of California Davis. And then I did a fellowship in clinical epidemiology at a joint program between University of California San Francisco and UC Berkeley. So that was my formal educational training. I got a lot more
09:52:54 training in the field, actually working in the -- working in the profession. But that was my formal training.
Q And have you consulted with medical device companies as a clinical epidemiologist?
A Yes, I have. I think with respect to medical products,
09:53:09 one focus of a great deal of my research and consulting is around the safety of products and methods of determining the safety of those products.
Q And have you taught general medicine and epidemiology to graduate or undergraduate level students?
09:53:26 A Yes, I have. I was on the faculty of the University of

09:53:29 California San Francisco, both in the departments of epidemiology and the department of medicine. And there I was the associate director of the clinical epidemiology fellowship program. Actually, the program I was trained in, I became the 09:53:45 deputy director of that. And so I taught graduate students and medical students at San Francisco. I continued that. I moved to the faculty at University of California San Diego, and taught there as well.

Q And have you practiced medicine?

09:54:02 A I have. I was very actively a member of the faculty practicing in the department of medicine at the university hospitals where I was. Generally those were county hospitals. And I spent probably about a third of my time in direct patient care.

09:54:16 Q And in your practice, your medical practice, did you ever implant an IVC filter?

A No, I didn't implant one, but I had patients who had -- one of my fields of study was actually risks for pulmonary embolism. And I had a patient who had one of the very early 09:54:36 filters implanted by someone else. But I'm not someone who can implant the filters.

Q Does your lack of experience actually implanting filters inhibit your ability to evaluate the sufficiency of information in medical literature to determine whether there 09:54:51 are reliable adverse rates reported?

09:54:55 A No, it does not.
Q Do you still hold an active medical license?
A I do. I've been continuously licensed in the State of California since 1976.
09:55:05 Q Are you board-certified in any medical discipline?
A Yes, internal medicine.
Q And in your background, in your experience, have you ever worked with the FDA, the Food and Drug Administration?
A I did. After about almost 15 years in different
09:55:21 University of California medical schools, I went to the FDA in 1992 and worked there for the next 12 years.
Q And can you briefly summarize the positions you held with the FDA over that period and describe for us generally what your responsibilities were in each position?
09:55:38 A Sure.
Well, my first position, to back up just a little, I was at San Francisco General Hospital when the AIDS epidemic came along. It came along and we didn't even know what it was. And I got involved with developing drugs and products
09:55:53 for the HIV epidemic.
And I was invited to be on advisory panels to the FDA, and when the position opened in 1991 to be the director of the division responsible for all of the AIDS drugs, my family and I packed up and we went to Washington, and I stayed
09:56:10 at FDA the next 12 years. And I worked on drugs for about

09:56:14 five and a half years, and during that time we approved the cornerstone HIV drugs that changed the epidemic.

Then for two years I was the deputy director at the Center for Biologics. Those are blood and vaccines and other

09:56:32 kinds of biological proteins.

And then for the last five years, I was the director of the Center for Devices and Radiological Health. And reported directly to the commissioner. But then I was responsible for medical devices. So I did that another five

09:56:44 years.

So those were my -- those, in brief, were my 12 years at FDA.

Q In the last position, what was -- what is the role of the Center for Devices and Radiological Health?

09:56:56 A Well, it's the -- that's the center that's responsible for all of the surgical equipment, all the implants, the Bard filters is an example of a medical device. Also, all of the radiology equipment, the X-ray equipment, the surgical tables. Everything from tongue depressors to very, very high tech

09:57:15 pacemakers.

The radiological health part of it, we were also responsible for products that emit radiation, not just medical, but also cell phones and theft detection devices and so forth. So very -- a very broad group of responsibilities.

09:57:31 And I was the overall director for that center. We had about

09:57:35 1200 employees.
Q And in your professional career have you lectured or presented lectures to professional organizations on topics involving medical devices?
09:57:46 A Yes, I have. Particularly since I was the director the device center. But even a bit before that, because I developed a couple medical devices back when I was an academic. But I've lectured to professional groups, I've lectured at universities, I still lecture here in Arizona from
09:58:06 time to time.
Q Are you still a part-time resident here in Arizona?
A I am. I've got a house in Ahwatukee. We came here after we left FDA to -- my wife accepted a position at TGen, a few blocks from here, the Translational Genomics Center, and I
09:58:27 followed her. And we -- at that time I started a consulting practice and also teaching on -- as a member of the volunteer faculty at the law school here.
Q Now, as a physician and epidemiologist, have you conducted medical research studies yourself?
09:58:46 A Yes, I have.
Q Can you describe for the ladies and gentlemen of the jury generally the types of medical studies that you have conducted.
A Within kind of a broad range. I have conducted and am
09:58:59 involved in a number of randomized controlled clinical trials.

09:59:05 These are studies that are planned in advance and where you've got a treatment group and a control group, and people randomly are assigned to the two, and then you follow them forward and see what the effect is of the new product you're studying, for 09:59:17 example.

I've also designed studies that are observational, where you identify a group of people, and then you have regular follow-ups and -- and collect the information in that way.

09:59:32 And I've also been involved in studies where I actually start with problems, and then look backwards and see if you can determine what those are.

So just about every kind of epidemiology study category there is, I've participated in, designed, and in 09:59:46 addition to the ones I've designed, I've reviewed many, many more.

Q And have the results of the research, the medical studies you've conducted been published?

A Yes, in peer-reviewed literature. Some of them for FDA 10:00:00 products and have resulted in studies that led to approval of products.

Q And have you yourself served as a peer reviewer for professional journals?

A I have.

10:00:11 Q Can you give us an example or two of the kind of materials

10:00:16 that you peer reviewed?
A I was a peer reviewer for the Journal of Medicine at one point. They would typically send me clinical trials in epidemiology studies. There's a journal once called
10:00:28 Controlled Clinical Trials, now called the Journal of Chronic Disease, I was peer-review editor for studies submitted there. Sometimes methodology studies. Other times clinical studies.
Q And in your professional career, have you had responsibility for evaluating studies of adverse events
10:00:47 associated with drug and medical devices?
A Yes. And actually several different ways. First I was an investigator, so I was responsible for filing safety reports to the FDA when I was an investigator. Then, when I was at FDA, we were responsible for evaluating the safety reports for
10:01:02 products we were responsible for in all three divisions and taking appropriate actions.

Then, when I became a consultant, I actually worked with companies setting up their reporting systems. For four years through the time I was a consultant, I was actually a
10:01:16 company official for two pharmaceutical companies. And in one of them I was directly responsible for the safety reporting. So I've been doing safety reporting for 35 years.
Q And are you drawing on that collective body of experience you've assembled over the last 30, 35 years in forming your
10:01:37 opinion in this matter?

10:01:38 A Yes, I am.
Q Now, are you being compensated for the time you've spent at our request --
A Yes.
10:01:44 Q -- to evaluate studies?
A Yes, I am.
Q And what are you charging?
A My current rate is $650 an hour.
Q And does it change as to whether you're sitting at your
10:01:54 desk reading a medical literature or sitting here testifying?
A No.
Q And how much have you billed in total in connection with your study of the medical literature of the IVC filters?
A I began working on this in December of 2010, and since
10:02:15 that time I've billed approximately $225,000.
Q Let's talk about some of the types of medical literature that you reviewed in doing your work in this matter. Can you tell us generally what it was, what body of materials you looked at.
10:02:32 A So I began -- there are search engines that allow you to actually find the medical literature. And they're run by the National Library of Medicine. So I began looking for the studies that had studied the Bard filters, and I pulled a collection of those studies, obtained the original papers, and
10:02:51 then began sorting those into different sorts of categories,

10:02:56 whether they were prospective trials, meaning that they started at the time of implantation and began following the patients, or whether they were retrospective studies that started later and looked back. Sorted them into different
10:03:10 categories and began to analyze them.

Q And do you know how many studies you actually looked at in forming your opinions?

A There's well over 100 studies that have -- the filters that are relevant to -- to Bard. There's actually over 2,000
10:03:28 papers about interven- -- caval filters. I made sure that I saw all the studies that I could find about Bard, and then I looked at some of the other studies just for comparison.

Q And as I understand what you've told us at the beginning, you were asked to see whether the medical literature was
10:03:52 sufficient to determine whether there were reliable rates for adverse events in Bard filters; correct?

A Yes, that's correct.

Q All right. What is your opinion, sir?

A Well, my opinion is that the adverse effects of IVC
10:04:09 filters, and Bard in particular, are well-known, and well described in the medical literature, but none of the studies have been designed in a way that they capture the information that allows them to actually say what the rate is. We know it's low, but there isn't information about -- none of the
10:04:28 studies are designed in a way that you can actually determine

10:04:32 the rate of overall complications or even specific complications like fracture or tilt. So the studies do not provide that information.

Q And with respect to that opinion, do you hold it to a

10:04:46 reasonable degree of scientific certainty?

A I do.

Q Let's talk, then, about as a clinical epidemiologist, what kind of information is needed to calculate a reliable rate for any adverse event in a particular medical device?

10:05:01 A It's actually quite simple in concept; it is just hard to do in practice. In concept you have to identify a population that got the filter. So let's say you were trying to do a study to determine the rate. You first want to start with everybody who got the filter, because that is going to be your

10:05:18 population to determine the rate.

A rate means that you also have the dimension of time accurately measured so that you know when things occurred and how many of them occurred.

And so that means that you have to have a study that

10:05:32 has regular follow-up. And because many of these complications can only be seen with X-rays of various kinds, you actually have to have scheduled X-ray follow-up to actually see, you know, what's happened to the filters at different points in time.

10:05:51 Instead, what the literature mostly has is a

10:05:55 collection of people that may have come to a hospital, but we don't know what population they represent. They may have complications, we don't have any idea of what time they occurred. And we have many, many missing data. There are
10:06:09 very few studies where they actually conduct the X-rays to look for them. So they use the X-rays that were taken as part of regular medical care and see what they can do.

So the studies just aren't designed in a way that provides that information where you can generate a rate.

10:06:25 Q Would you describe the various types of medical studies that researchers do if they're trying to evaluate medical devices.

A Sure.

You can think of studies kind of in a hierarchy, from
10:06:38 the most reliable to the least reliable. You learn something from all of them, but the most reliable ones are the ones that actually can give you quantitative data and rates to -- and the others give you just sort of more descriptions of things that have happened.

10:06:52 So at the top of the hierarchy are --

Q Dr. Feigal, let me interrupt you, if I can. Would it be helpful for you to step down, with the Court's permission, and provide the list of studies, writing it out on the board, and then returning to the seat to talk about each of them?

10:07:07 A I'd be happy to do that.

10:07:11 MR. CONDO: Your Honor, may he do that?
THE COURT: He may.
THE WITNESS: Handwriting test.
BY MR. CONDO:
10:07:20 Q Let me ask you the question: What is it that you are going to be writing on the white board, sir?
A I'm going to list the studies from the most reliable designs to the least reliable and the least helpful.
Q Okay. Thank you. Would you please do so.
10:08:12 A So the first is -- the perennial problem is finding a marker that's not --
Q Try this one.
A Here's an RCT, which stands for randomized control trial.
And here you start with a population, and you
10:08:40 basically -- the fancy way of flipping a coin, and you divide them into two groups, and then you follow them forward to see what happens to this group and what happens to that group. And some of them may have side effects in both, and you look at the differences. And this is very reliable because you are
10:09:01 starting with people who are all the same.
The next best are prospective cohort studies. And here, you take two groups, but you don't randomize them. In this case you might take patients with different filters. They might have different filters for different reasons. It
10:09:25 may be a certain filter that's used in cancer patients more

10:09:28 frequently, for example, or by one operator, one surgeon or another. And then you follow them. And then you see, again, if there's a difference between the two.

Then there are the prospective uncontrolled studies. 10:09:59 So now we just have one group. And we don't have a comparison, but we just have one group. And we can at least say -- and these are still very useful. You can say of all of the people that use this, if we follow them systematically to find out what the complications are, we can at least find out 10:10:15 what happens if you get this filter. We won't know about any other filter.

Then there are the studies that are just case collections. And a lot of those are retrospective. In fact, start out here, and they look back to see what kind of -- you 10:10:42 know, if they have patients that are in their clinic, they can take just a sampling of all of the patients that are still in the clinic and look back, how long have they had the filter? What kind of problems have they had?

Problem here is you get a lot of lost follow-up, a 10:10:58 lot of patients that are missing. And there are people who actually try and do these prospective studies retrospectively. So that's another list on the list, the retrospective.

And there are examples of that that we can see in the literature, where they look backwards. Everything has already 10:11:22 happened. Again, they're really bedeviled by missing data.

10:11:27 And then you have some studies that just study cases and just report on what's happened on those cases. So that's common. Like retrieval studies. People come in, they're going to have their filter out, people look at the filters and
10:11:42 say, what shape are the filters in? They don't have any information about people not coming in for retrieval, and the retrievals are all different times. They don't have any real ability to do rates. But you learn something. You learn a lot about how to do retrievals.

10:11:56 And then, finally, you have single cases.

MR. O'CONNOR: I'm sorry, I didn't hear that, Your Honor.

THE WITNESS: Single cases.

MR. O'CONNOR: Thank you, Doctor.

10:12:14 THE WITNESS: There are databases of collections of single cases. And there are some single case reporting that has to go to the FDA. Those actually tell you very little, except what happened to a single patient. You can't really generate rates or comparisons, and FDA talks about that.

10:12:29 So this is the rough hierarchy of studies.

MR. CONDO: May I move this board back just a little bit?

THE COURT: Yes.

MR. CONDO: Thank you.

10:12:45 BY MR. CONDO:
Q For reliability in determining reliable rates for adverse events, how would you describe the randomized control trial? How is it referred to generally?
10:13:08 A It's referred to the gold standard of clinical evidence because you've controlled for the differences in patients at baseline, and because they're prospective studies where you have a planned data collection over time and you're collecting it the same on all the patients. And when they're well
10:13:25 executed, that's the best source of data.
Q And in your review of the medical literature, has there ever been a randomized controlled trial for IVC filters?
A There has not. The challenge is you have to randomize patients to perhaps not get a filter, and you'd have to find
10:13:44 patients who you could either not put a filter, put a filter in, and it would be ethical to do either one.
So it is very difficult to do a randomized controlled trial for some types of products, and this is one of them.
Q Can you calculate rates or occurrences from each of these
10:14:04 types of studies?
A You can calculate them from the randomized control trial for the duration of the trial. You can calculate them from the prospective cohort studies, where you have a control group and you have systematic collection over time. But
10:14:20 unfortunately there aren't any of those either that have

10:14:24 compared two products.

So with all the rest what you have is you have a report of adverse events that have occurred in a group of patients, but you don't have the time element, and you're 10:14:35 often missing patients. There just isn't a way to calculate the rates in those types of studies.

Q As a clinical epidemiologist, what does one need to do in order is to design a study that would generate reliable rates for adverse events for an implantable device like an IVC 10:14:57 filter?

A You have to have a population you define. So that is sort of obvious, it's the people that need an implanted filter. And it would probably be at participating institutions. Ideally you'd like everybody, particularly if it is an 10:15:10 observational study. But patients do have to consent to be in a study.

Then you'd have to have outcomes that you're going to measure, and a good measuring technique. You'd want it to be the same across different patients. So you could use a CT 10:15:23 scan, for example. You could use other kinds of -- other kinds of X-rays. And you'd want to have a reliable methodology to do the statistical analyses and calculate all of these things. It would basically be a prospective protocol. The best would be at the time of implantation.

10:15:47 Q Do you have to have a defined population of participants

10:15:51 in the study?
A Well, you do. For example, if a center just reports its retrievals, they don't know where those patients all came from and they don't know all the patients that didn't come in for
10:16:04 retrieval. So you can't get a rate from retrieval studies, for example.
Q Do you need a defined group of representative patients for a reliable study?
A Yes. You need to have the patients that are typical of
10:16:21 the patients that receive the device.
Q Yesterday, or perhaps two days ago, there was some questioning of Mr. Van Vleet about a published study known as the Nicholson study. Is that one of the medical literature, part of the medical literature that you examined as part of
10:16:53 your investigation in this matter?
A I did, yes.
Q What was that study about?
A This was a study at York Hospital in Pennsylvania. A cardiologist there had seen an unusual patient who had a
10:17:12 fracture that had gone to her heart, and he decided to actually call back the patients who had had filters placed at his hospital for a period of time. And then he published the results of what his findings were from that study.
Q Were there problems with that study?
10:17:44 A There were a lot of problems with that study. First we

10:17:49 start with the population. He stated, and some of this was later -- what actually was done in the study was actually later discovered by requesting the records from the study as part of the trial process. But what -- what he did was he not
10:18:11 only did not have all of the patients from York Hospital, he only had about two thirds of them, and he deliberately excluded patients from certain implantation areas, such as the intensive care unit. Sometimes they were placed at the bedside in the intensive care unit.

10:18:29 But he also not only didn't have all the patients, he had groups of patients we know didn't have fractures. And he excluded them from his study. He should have included them if he wanted the rate. But he deliberately excluded them.

And then he added other patients in who weren't from
10:18:51 York Hospital to his study who he knew had fractures. And so the numbers just -- you know, at the end of that, you just didn't really know what he had done because he had both increased the number of fractures, decreased the number without fractures, was missing a large amount of data. He
10:19:09 didn't even accurately represent how many different surgeons were involved in placing the devices.

Q What do you mean he didn't accurately represent the number of surgeons involved in placing the devices?

A When he published the study, he said one of the strengths
10:19:25 of the study was that many, many different operators, many

10:19:30 different surgeons had been involved in placing the fractures -- placing the devices that had fractured, placing all of the devices.

What was later shown was 85 percent of them were a 10:19:43 single operator. Single surgeon. He actually published a retraction for his published paper after saying that he had been mistaken about that with the earlier publication.

But rather than the inexperience of multiple people implanting these, it was really a study of a single hospital, 10:20:02 and largely of a single surgeon, and that is not one you would sort of say, gee, I bet that is representative of the results everybody's going to get.

Q In your opinion, was the Nicholson study -- can it be relied upon for scientifically reliable data?

10:20:21 A No. The only use of the study is that he has some detailed descriptions of the individual patients, and I think he accurately represented the experience of those individual patients. But as a study to estimate rates or proportions, it's not useful. It's -- you can't rely on those numbers.

10:20:43 Q Now, final question: In the studies, the hundred or so studies you reviewed or looked at involving IVC filters, did you find any studies that met all of the requirements that you said are necessary to determine an accurate rate for the adverse events that existed?

10:21:04 A There is one study that was limited because it's very

short-term, but one of the studies that the company sponsored was the study on how to retrieve the filters. And so in multiple institutions approximately 100 people were followed until the time of removal, which was between three and six months. At the time of removal, for example, they found one fracture.

That's the only study. And it only tells us about the experience over a very short, short time period. But that's the only study that actually had a systematic enrollment, and then a defined follow-up, but it's small. This is not a very common -- these are not very common events. You have to do large studies to find very many of these.

And so it doesn't really give us -- that one fracture doesn't tell us what the fracture rate is even at three months because it's just not enough information.

Q So there really was no study that you found that allowed you to identify a reliable fracture rates for IVC filters; correct?

A That's correct. Not for Bard and not for the other filters that are used.

MR. CONDO: Thank you.

No further questions, Your Honor.

THE COURT: Cross-examination?

MR. O'CONNOR: Yes, Your Honor.

10:22:21

C R O S S - E X A M I N A T I O N

BY MR. O'CONNOR:

Q Hi, Dr. Feigal. My name is Mark O'Connor.

A Good morning.

10:22:33

Q I think what you just said, and I appreciate what you told us about the hierarchy of studies, but you do agree that regardless of the hierarchy, studies are relied upon by both -- by the medical community; correct? Doctors do read them and rely upon them?

10:22:52

A For different purposes, yes.

Q And medical device companies should keep itself apprised of the current status of medical literature. Is that fair?

A Yes, that's fair.

Q Thank you.

10:23:05

Now, Nicholson is still cited in literature today; correct?

A Yes. Unfortunately, although he retracted the information about the multiple surgeons, he actually never published a correction to his paper that actually identified all the other

10:23:26

errors. So, yes, it is still cited.

Q And he did, as you said, send a retraction. Fair?

A Yes, on one very small point -- well, it a very important point, on the point that he was actually reporting the experience of a single surgeon.

10:23:40

Q And I think what you told us that at least Nicholson did

provide a detailed description of the failures that were seen in the study for the Recovery and the G2 filter; correct?

A There's a detailed case for a couple of the patients, and then a description of some of the others, yes.

Q And his conclusion was that there was a high prevalence of fracture and embolization in both the Recovery and G2. Fair?

A I don't recall if that was -- if that was his conclusion, but there was no data in his study that would have allowed him to estimate the prevalence or the incidence or the rates, three different ways of talking about how often things happen, from the patient population even at York Hospital, because he didn't study them all or didn't study them properly.

Q I understand. But there's a difference between observing events in patients and rates; correct?

A Yes. You can simply count up the number of patients that you have, and so I'm not disputing the number of patients that had fractures, it's just you can't get rates or proportions out of those.

Q So you're not disputing that Dr. Nicholson didn't see patients that had failures in both the Recovery and the G2; is that correct?

A Well, by failure, you mean he observed fractures, which, in some cases, migration, yes. I'm not disputing. He did observe that and he did describe that in a little over a dozen patients.

10:25:04 Q All right. And, as a matter of fact, there is literature out there that talks about fractures and migration of both the Recovery and G2; correct?

A Yeah. There are multiple papers that describe individual 10:25:17 patients who are -- or collections of patients. And these aren't papers where you get rates or proportions.

Q But, again, papers that describe those failures by doctors who observed them with patients with G2 and Recovery?

A Yes, that's correct.

10:25:30 MR. O'CONNOR: That's all I have. Thanks.

THE COURT: Redirect?

MR. CONDO: No redirect, Your Honor, but for the trial record, may we have marked the hierarchy of events as Exhibit 7949 and offer it as a demonstrative exhibit only?

10:25:46 THE COURT: Any objection to this being a demonstrative?

MR. O'CONNOR: No objection.

THE COURT: All right. What's the number?

MR. CONDO: 7949.

10:25:54 THE COURT: Okay.

MR. CONDO: Thank you, Your Honor.

May I move this?

THE COURT: Yes, you may.

Thank you, sir.

10:25:58 THE WITNESS: You're welcome.

10:26:21 MS. HELM: Your Honor, at this time we call Dr. John DeFord by video.

Dr. John DeFord is a senior vice president for science, technology and clinical affairs at C.R. Bard, Inc. 10:26:42 In this role, Dr. Ford is responsible for the research and development functions at the various divisions of C.R. Bard. Dr. DeFord obtained both master's -- I'm sorry, both bachelor's and master's degrees in engineering before obtaining his Ph.D. in electrical biomedical engineering in 10:27:02 1990.

Prior to joining Bard in 2004, Dr. DeFord held various positions at other medical device manufacturers, including serving as president and CEO of Cook, Inc.

(Video testimony played.)

10:29:41 THE COURT: Let's stop the video.

We'll take the morning break, ladies and gentlemen. We will resume at 10:45.

(Recess taken from 10:29 to 10:46.)

THE COURT: Thank you. Please be seated.

10:47:30 You may continue with the deposition.

(Video testimony played.)

MR. NORTH: Your Honor, at this time we call Dr. Clement Grassi to the stand.

10:59:23

CLEMENT GRASSI, M.D.,

called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

10:59:25

BY MR. NORTH:

Q Good morning, Dr. Grassi. Could you please tell the members of the jury what your profession is.

A Yes. I am a practicing interventional radiologist.

Q And have you been retained by Bard as an expert witness in

10:59:48

this particular matter?

A Yes.

Q And what is the focus of your opinions in this particular case?

A The focus of my opinions is to speak to the guidelines for

11:00:01

percutaneous inferior vena cava permanent placement.

Q Where did you attend college, Doctor?

A Harvard College.

Q Where did you go to medical school?

A Tufts University School of Medicine.

11:00:17

Q After medical school did you complete an internship for additional training?

A Yes, I did. Following medical school I was at the Massachusetts General Hospital.

Q And is Massachusetts General Hospital, is it affiliated

11:00:32

with a university?

11:00:33 A It is. It is one of the teaching hospitals of Harvard Medical School.
Q And did you complete a residency in radiology?
A I did. That was at the Beth Israel Deaconess Hospital in
11:00:46 Boston.
Q And did you complete fellowship training after that?
A Yes.
Q And where was that? Where did that take place?
A That was at Brigham and Women's Hospital in Boston, also
11:01:00 an affiliate of Harvard Medical School.
Q After completing your fellowship training, did you hold any academic appointments?
A I did. I was an instructor in radiology with Harvard Medical School, and subsequent to that an assistant professor
11:01:20 in radiology with Harvard Medical School.
Q Now, tell us where you currently work, Dr. Grassi.
A I'm currently with Hallmark Health, which is a group of two hospitals in the Greater Boston area.
Q And what do you do with those hospitals right now?
11:01:38 A I practice interventional and vascular radiology.
Q Are you licensed to practice medicine?
A Yes, in the State of Massachusetts.
Q And are you board-certified?
A Yes, I am. I'm board-certified with the American Board of
11:01:55 Radiology, and I have a certificate of added qualifications in

11:01:58 interventional and vascular radiology.
Q And what does is it mean to be board-certified, Doctor?
A It means that the physician has passed a series of education and testing so that he or she fulfills the
11:02:16 qualifications of the profession.
Q And how long have you been practicing medicine?
A About 38 years.
Q Today, as a practicing interventional radiologist, what sorts of procedures do you handle on a routine basis?
11:02:32 A I handle vascular procedures of a wide variety, including inferior vena cava filters, placement and retrieval, as well as a wide variety of nonvascular procedures in the abdominal, biliary, and other systems.
Q Have you held leadership positions, professional
11:02:58 leadership positions, during the course of your practice?
A Yes. I have been a director with the Boston VA system. As well I've been a director of vascular and interventional radiology with the UMass Memorial System. And as well as that, previously I have been a coordinator for residents and
11:03:29 fellows in their training with the Harvard Medical School System at Brigham and Women's Hospital.
Q Dr. Grassi, are you familiar with the organization called Society of Interventional Radiology?
A Yes.
11:03:46 Q Can you tell us briefly what that organization is.

11:03:50 A Society of Interventional Radiology is an international organization and it works to educate, promote, and deal with issues in the profession of interventional radiology.
Q Are you a senior fellow of that organization?
11:04:08 A Yes, I am.
Q What does it mean to be a senior fellow of the Society of Interventional Radiology?
A To be a senior fellow, one must have achieved academically and in medical practice certain parameters, and by application
11:04:27 and review with peers in the society, one submits an application and then is accepted for that position.
Q And for how many years have you been a senior fellow of the Society of Interventional Radiology?
A I would have to check the exact date, but it's been for
11:04:49 over 25 years now.
Q Now, is the Society of Interventional Radiology sometimes referred to by its acronym, SIR?
A Yes, it is.
Q Have you served on any committees over the years with the
11:05:07 SIR?
A I have. I've been a member of the Standards of Practice Committee and also with the Technology Assessment Committee of the SIR.
Q And how long have you been a member of the Standards of
11:05:21 Practice Committee for the SIR?

11:05:25 A Again, I have been, on a rotating basis, a member of that committee per their policy for over about 20 years now.
Q What does the Standards of Practice Committee for the SIR do?
11:05:45 A The Standards of Practice Committee directs itself to educate, promote, and organize information for the society members, that is interventional radiologists, as well as all interventional radiologists on various topical areas in the profession.
11:06:10 Q Now, have you ever served as the chairperson of the Standards of Practice Committee for the SIR?
A Yes.
Q In what time frame did you serve as the chairperson?
A It was subsequent to 2002.
11:06:29 Q Now, while you were the chairperson of the Standards of Practice Committee, did that committee develop or publish any guidelines regarding IVC filters?
A Yes. During the time period that we're talking about, and that is prior to 2001, the SIR commissioned and developed the
11:06:58 guidelines for percutaneous permanent inferior vena cava placement.
Q Now, was that your first experience with IVC filters?
A No, it wasn't.
Q Tell us a little bit about your professional experience
11:07:13 with IVC filters over the years.

11:07:17 A Well, as a diagnostic radiologist, which I am, I started looking at IVC filters on an observational basis, and as an interventional radiologist I have placed the devices, as well as retrieved the optional retrievable type of filters in many
11:07:40 patients.

Q Over the years, have you published articles concerning IVC filters and venous thromboembolic disease?

A Yes.

Q Can you estimate for us approximately how many articles
11:07:53 regarding that device and disease state that you have published?

A It would be now approximately a dozen.

MR. NORTH: If we could bring up Exhibit 7312.

BY MR. NORTH:

11:08:16 Q Dr. Grassi, while you served as chairperson of the Standards and Practices Committee for the SIR, did you and your committee develop the guidelines that are now being shown on the screen in front of you as 7312?

A Yes, we did.

11:08:43 Q And tell us what the official title of these guidelines were.

A The official title is Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism.

11:08:58 Q Prior to the development of these guidelines, were there

11:09:01 any guidelines for the placement of IVC filters?
A Although there was certainly a lot of commentary in the medical literature, hundreds and hundreds of articles on the subject of IVC filters, there was no dedicated synopsis or
11:09:21 summary for practitioners or those who work with IVC filters in the field.
Q And were these guidelines eventually published?
A Yes, these were.
Q And where were they published, Doctor?
11:09:36 A They were published in the JVIR, which is the Journal of Vascular and Interventional Radiology, which is the official journal and publication of the SIR. That is, the Society of Interventional Radiology.
Q And do you consider the JVIR journal to be a reliable
11:09:57 journal?
A Yes, I do.
Q Are the articles that are published in that journal peer-reviewed?
A Yes.
11:10:06 Q Were you joined by another -- a number of other interventional radiologists on this committee in developing these guidelines?
A Yes, I was.
Q Can you tell us briefly a little bit about the other
11:10:21 members of the committee that worked with you on this project?

11:10:24 A The other members were colleagues and very talented interventional radiologists from across the country who worked as a committee group for the development of these standards.

Q Tell us a little bit about the process of developing these

11:10:46 standards. How long did it take to do so?

A Well, this was a rigorous process because, as one can understand, the SIR, as an international committee, wanted the committee to give its full efforts on this project. It extended over a minimum of 18 months. It started with the SIR

11:11:14 staff looking for all of the available medical literature that is by PubMed, Google Scholar, and other search engines. Hundreds of articles were identified.

The committee then --

MR. JOHNSON: Excuse me, Your Honor. This is

11:11:36 nowhere contained in this expert's report; it's not in his deposition.

THE COURT: Is it in the report, Mr. North?

MR. NORTH: Yes, Your Honor. Page 11, there's an entire paragraph about the development of these standards.

11:11:49 THE COURT: Could I get a copy, please.

Objection is overruled. The testimony so far, I believe, has been within the large middle paragraph on page 11 of the report.

BY MR. NORTH:

11:12:35 Q At the time that the guidelines were being developed, were

11:12:38 there any retrievable filters available on the market?
A No. In this time frame, permanent vena cava filters were the devices which we were using because the retrievable or option type filters came later.
11:12:55 Q As a part of this effort to develop the guidelines, did you and your colleagues look at the medical literature concerning complications and trackable events?
A Yes, we did.
Q And were complications and trackable events regarding
11:13:17 filters known to you and your colleagues at the time that you were developing these guidelines?
A Yes. We were well familiar with them because of the fact that there were complications or other events that had been encountered by practicing interventional radiologists.
11:13:40 Q What is the difference between complications and trackable events?
A Well, a complication as defined in the guidelines document was an adverse event which would have a patient effect.
In the course of our going through, as you can
11:14:00 understand, this abundant scientific literature, there were other parameters we studied, and it was the committee's decision to call these trackable events because it must be understood that they would be events that either might cause an adverse event or might cause no adverse event for the
11:14:23 patient. That is, the patient would be asymptomatic.

11:14:25 For the purpose of completeness of the paper, we felt it was important to also include these in the publication.

Q As a part of your paper, did you publish tables regarding the complication rates and the trackable event rates?

11:14:50 A Yes, we did.

MR. NORTH: If we could -- let's go to the next page.

I'm sorry, the next page.

Your Honor, at this time we would like to have

11:15:04 permission to talk about the content of this pursuant to 803(18). We may separately move for admission of the entire document at the conclusion of the testimony.

THE COURT: Well, I don't know what you're asking when you say "talk about."

11:15:18 MR. NORTH: I would like to tender this as an exhibit with the understanding right now that it's coming in under 803(18). It would come in under that and therefore could not be displayed to the jury.

THE COURT: 803(18) doesn't allow it to be

11:15:32 displayed. Are you asking it be displayed?

MR. NORTH: No. No.

THE COURT: What do you mean when you say you're tendering it as an exhibit?

MR. NORTH: Well, to be able to have him talk about

11:15:41 the content of the document.

11:15:43 THE COURT: So you want to ask him questions about the content of the table?

MR. NORTH: Exactly.

MR. JOHNSON: No objection, Your Honor.

11:15:49 THE COURT: All right.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH:

Q If we look at table 1 in this document, what does this table list?

11:16:01 A This table lists different complications which have been reported in the literature and associated with patients who have received inferior vena cava filters.

Q And how did your committee go about determining what had been reported in the literature?

11:16:21 A Well, from the hundreds of articles which I've mentioned, the group of articles was reviewed by the committee and summarized or boiled down to a more select group of citations and references. We grouped these which we felt were the most pertinent to the document. And those are some of the

11:16:44 citations and references in the parenthesis that you see listed.

Q What -- you list by these various complications reported rates. Are those the ones that you saw in the medical literature?

11:16:59 A Yes. Correct.

11:17:01 Q And then you also list for each complication a threshold percentage. What is that?

A That is, in the context of the document, a threshold number which we included in order to be helpful and useful to

11:17:17 those who work with inferior vena cava filters.

So as stated in the text portion of this document, the numbers that you see under the threshold would be used by an individual working with IVC filters, such as an interventional radiologist, and that would trigger that person

11:17:38 to see if in his or her practice they should conduct their own quality assurance or further review as to the types of complications that was occurring. And we felt this was necessary for patient safety.

Q And in the committee's investigation, what did you

11:17:59 determine were the reported rates of death associated with IVC filters?

A The reported rate was 0.12 percent.

Q Did you also determine reported rates for filter embolization?

11:18:18 A Yes.

Q What is filter embolization?

A Filter embolization would be a movement with -- abnormal movement of the filter device to a different location than its intended position.

11:18:34 Q Would that include migration of the filter to the heart?

11:18:37 A Yes.
Q And what did you see as the rate -- reported rate, you and your committee, of filter embolization in the literature?
A 2 to 5 percent.
11:18:55 Q If we could look at table 2, please.
And what does table 2 present as a part of the SIR guidelines?
A Table 2 represents other trackable events. And as I had mentioned earlier, these would be events which, for
11:19:19 completeness of the paper, we included. They may have been associated in the world literature with an event from a patient or they may be things which were observed scientifically, but the patient had suffered no injury and had no symptoms or signs.
11:19:37 Q And, again, did you look at -- did you and your committee look at the medical literature to determine the reported rates for each of these trackable events?
A Yes, we did.
Q And what did you determine was the reported rate for
11:19:55 fracture of filters?
A The reported rate for fracture was between 2 and 10 percent.
Q Did you determine a reported rate for migration?
A Yes. Between zero and 18 percent.
11:20:12 Q And did you determine a reported rate for IVC penetration?

11:20:20 A Yes. Zero to 41 percent.
Q Did your committee -- did you and your committee make any observations as to whether penetration and migration events were customarily significant from a clinical perspective?
11:20:40 A The committee recognized, since it was composed of practicing interventional radiologists, that these are commonly observed events, seen when inferior vena cava filters are used.
Q Do you know what -- in determining the reported rates for
11:21:04 filter fracture, what medical articles you cited for that?
A Well, originally there were many articles referred to, and two articles were cited here on table 2 for filter fracture, references number 17 and 24.
MR. NORTH: Could we look at the final page at what
11:21:31 those articles were, the citations.
Let's go back one page, please.
BY MR. NORTH:
Q What is citation 17 that the committee cited as a basis for -- one of the bases for the reported rates for fracture of
11:21:50 2 to 10 percent in filters?
A That would be the article written with the first author, Dr. Ernest Ferris, and others, titled Percutaneous Inferior Vena Cava Filters, a Followup of Seven Designs in 320 Patients.
11:22:10 Q Are you familiar with that article?

11:22:12 A Yes, I am.

MR. NORTH: Could we show 7002 to the witness, please.

7002.

11:22:27 BY MR. NORTH:

Q Is this a copy of the Ferris article we just referenced?

A Yes.

Q If we could turn to table 2 in that article.

Did the Ferris -- well, first of all, where was the

11:22:48 Ferris article published, do you know?

A Yes. That was published in the Journal of Radiology, the so-called Gray Journal of radiology, which is the major publication for the Radiological Society of North America, commonly referred to as the RSNA.

11:23:08 Q And do you consider that a reliable journal?

A Yes, most definitely.

Q Are the articles published in that journal peer-reviewed?

A Yes.

Q Now, in reviewing various types of filters, do you know

11:23:27 what these abbreviations Dr. Ferris is using for, let's say, BN-1?

A Yes, I do.

Q What is that?

A That would be the so called Bird's Nest or Gianturco-Roehm

11:23:44 Bird's Nest filter version number 1.

11:23:47 Q And what fracture rate did he find for the Bird's Nest?
A A rate of 4 percent is reported.
Q And what is the BN-II? Is that another Bird's Nest?
A Correct. The Bird's Nest filter version number 2.
11:24:05 Q And what did he find in his study the fracture rate for the Bird's Nest II filter to be?
A 3 percent.
Q Do you know what the A filter is referring to?
A That refers to the so-called Amplatz filter, which is not
11:24:24 clinically used. That is, in use today in the United States.
Q And do you know what he was referring to with the N abbreviation?
A Yes, I do. That's a short abbreviation for the Simon Nitinol filter.
11:24:41 Q Doctor, tell us what Dr. Ferris found as the fracture rate in his study for the Simon Nitinol filter.
A The fracture rate is 12 percent.
Q Is that higher than the range reported in the SIR guidelines?
11:25:00 A It is slightly higher because, as we've seen previously, the range was cited as up to 10 percent. And that is basically because the committee felt in viewing ranges that the most common range that we observed was up to approximately 10 percent. So it is slightly higher in the exact number.
11:25:27 Q Did the Ferris article in table 2 also discuss various

11:25:32 rates of -- reported rates of IVC penetration by various filters?

A Yes, it did.

Q And what did it report to be the penetration rate for the

11:25:43 Simon Nitinol filter?

A The Simon Nitinol filter penetration rate is reported at 33 percent.

Q And, again, what did the SIR guidelines that you spearheaded the development for, what did they report as the

11:25:59 reported rate for IVC penetration?

A That range, as I remember from our previous table, this number in the -- in the range reporting.

Q Were these complications and trackable events that you reported about in the SIR guidelines, were they known to you

11:26:25 in the medical community prior to developing those guidelines?

A Yes, they were.

Q Are those, the potential for those complications and adverse events, taught to residents and fellows as a part of their medical training?

11:26:46 A They are, and I was one of those persons, since I've worked in academic hospitals, who had the privilege of working with residents and fellows and trainees. And so we would go through these numbers and this data with them to help with teaching.

11:27:06 Q What happened once your committee developed a draft of

these guidelines?

A Once a draft was produced by the committee -- and I might say this method included telephone conversations, in-person meeting at two national annual society meetings -- the draft was then submitted to the executive committee of the SIR. Simultaneously, the guidelines were posted on the SIR website. Commentary was invited.

This was accessible to SIR members, that is interventional radiologists, non-SIR members, and basically anyone working with IVC filters who would like to read about it on the website.

After the commentary, the comments were collected and the guidelines draft, plus commentary, was passed on then to the JVIR, which I mentioned is the official journal. And that was reviewed by the editor and his staff among peers.

Q So was the article peer-reviewed before it was published?

A Yes, it was. In addition to our committee reviewing it.

Q And you say it was made accessible to the members of the SIR. Can you tell us approximately how many radiologists -- interventional radiologists belong to the organization?

A Yes. Well, thinking back to the time period of about 2001, at the time of the guidelines, there were over 5,000 members.

Q And in what year were these guidelines published, Doctor?

A They were published in 2001.

11:29:01 Q Does membership in the SIR entitle you to a free subscription to the JVIR?

A It does because members previously received a print version of the journal as well as online access.

11:29:17 Q So would all 5,000-plus members of the Society of Interventional Radiology at the time in 2001 that your guidelines were published, would they have received a copy of the Journal of Vascular and Interventional Radiology publishing those guidelines?

11:29:37 A Yes, that's right.

Q Doctor, has the SIR updated those guidelines since 2001?

A Yes, they have.

Q Were the ones that you were the chairperson of the committee and developing, were those republished in 2003?

11:29:55 A That's correct. In what was called a supplement to JVIR, they were published once again.

Q And was the most recent update published in 2017?

A Yes.

Q Dr. Grassi, were the SIR guidelines ever intended to

11:30:14 establish acceptable thresholds for IVC filter complications?

A No. The purpose of the committee and of the guidelines document was to educate, inform, and basically summarize information for those working with IVC filters. We felt that by publishing this information it would be very helpful to

11:30:43 those practitioners.

11:30:48 Q And what was your committee's expectation as to how the guidelines would be utilized once they were published?
A We intended that they would be a resource to anyone working with IVC filters, and specifically for interventional
11:31:14 radiologists it would allow them to look at our numbers, review their own practice, and see, practically speaking, if there was any reason for them to do their own personal quality review and whether it was necessary for them to review their day-to-day practice.
11:31:40 MR. NORTH: Could we display 6842.
BY MR. NORTH:
Q Do you recognize the document that is being displayed in front of you, 6842?
A Yes.
11:32:04 Q And what is this?
A This is the joint ACR, SIR, and SPR -- ACR stands for the American College of Radiology, a major radiological organization. SIR, we've talked about. And SPR is the Society of Pediatric Radiology. These are practice parameters
11:32:28 for the performance of inferior vena cava placement for the prevention of pulmonary embolism.
Q And are these essentially an update of the guidelines you first published in 2001?
A Yes.
11:32:43 MR. NORTH: And let's go to the next page, if we

could.

Let's go to the last page, if we could.

Back one.

BY MR. NORTH:

Q Doctor, I'm having a hard time finding it. Where is the list of authors? Would that be at the conclusion before the citations?

A I believe you have it displayed now.

Q The Comments Reconciliation Committee, what would that have been?

A That would be the committee that dealt with this document. To put this in a little bit of context, the ACR, American College of Radiology, would draw on the expertise of SIR members such as myself in formulating these documents. So this group of doctors with the names listed would have reviewed and then also looked at comments and incorporated those comments in the final document.

MR. NORTH: If we could go back one page, I believe there's another list.

BY MR. NORTH:

Q Does this provide the names of various physicians who worked -- from all of these different organizations that worked on these guidelines?

A Yes, it does.

Q From the SIR, would it have been the practice -- Standards

and Practices Committee that you had formerly been the chair of?

A Yes. The ACR committee would have drawn on interventional radiologists, as I mentioned, with their names included in this second paragraph, as well as elsewhere, and they made use of their input in formulating the ACR document proper.

Q And where were these guidelines, or parameters, as they're called, published?

A This goes out as a separate publication, as I understand, in booklet from the American College of Radiology. So it is a stand-alone publication on practice parameters as a guide to doctors and those working with these procedures.

Q Would you consider this to be a peer-reviewed publication?

A Yes.

Q And would you consider the American College of Radiologists as the publisher of these guidelines to be a reliable source?

A Yes, they are.

Q If we could look back, I believe there is a table 1 and table 2 in this article.

Did this particular group updating these guidelines also look at complications reported in the literature?

A Yes.

Q And did they publish a similar table than the one you had published?

11:36:05 A Yes, it is.
Q And did they publish a reported rate for death involving IVC filters?
A Yes.
11:36:16 Q Was it -- did it differ from the rate that you had published in your guidelines 16 years earlier?
A No, it doesn't. It is also 0.12 percent.
Q And did they also set forth a threshold for death in these guidelines?
11:36:39 A Yes, they did. They set a threshold of less than 1 percent.
Q And then if we could look at table 2 in the 2017 parameters.
What did the authors in the updated parameters or
11:37:00 guidelines identify as the reported rate of filter fracture in the medical literature review?
A Yes. They reported a filter fracture rate with a range of zero to 50 percent.
Q And what rate did they report in these 2017 guidelines for
11:37:23 migration of the filter?
A The rate of migration of the filter is reported at zero to 25 5 percent.
Q And at what rate did they report regarding IVC penetration?
11:37:41 A The reported rate of IVC penetration is zero to

11:37:46 100 percent.

Q Are these reported rates based on all types of filters or just certain filters?

A These would be based on a variety of many different 11:37:59 filters.

Q And do these updated guidelines, with the advent of retrievable filters, do they include both permanent and retrievable filters?

A Well, our original guidelines were geared, as I mentioned, 11:38:17 to permanent inferior vena cava filters. And it's my understanding from this document, and I would have to double-check the exact date, that these dealt with permanent filter devices, or at least with the filters available as of the exact date of this publication.

11:38:43 Q And would retrievable filters have been available as of that date?

A Well, you'd have to actually help me out on the reference date of this particular document.

MR. NORTH: Let's look at the final page of this. 11:39:08 Go back one.

BY MR. NORTH:

Q Let's look at, for example, number 9. Reference number 9.

That includes a citation to an article dealing with retrievable filters; correct?

11:39:39 A Yes, it does.

11:39:44 So that our having double-checked -- and thank you -- this document would include permanent devices but would also by its date include by incorporation retrievable type IVC filters.

11:40:04 Q Doctor, have you reviewed the references in the 2017 parameters here that we've been looking at?

A I have either seen, read, or encountered many of the articles and citations which are referenced, yes.

Q Do you know whether any of the articles talking about

11:40:29 fracture and reporting a rate of zero to 50 percent involve the Bard G2 filter?

A Yes. They would include the Bard G2, as well as others.

Q Now, you had told us that the American College of Radiologists was involved in this particular parameters being

11:40:50 developed.

A Correct.

Q Do you know approximately how many members, doctors or physicians, belong to the American College of Radiology?

A I would have to check myself as to the exact number, but

11:41:05 just to give you an estimate, the American College of Radiology, since it includes thousands of diagnostic radiologists as well as interventional radiologists, would be even a larger society group than the SIR.

Q And would this particular parameter -- parameters, as a

11:41:31 separate publication, have been distributed to all of those

physicians that belong to that organization?

A Yes. These parameters in print or electronic form would be available to all American College of Radiology members.

Q Doctor, do you hold the opinions you've given today to a reasonable degree of medical certainty?

A Yes.

Q And do you charge us an hourly rate for your consultation in this matter?

A Yes.

Q And what is that rate?

A A rate of $350 an hour.

Q Thank you, Doctor.

MR. NORTH: Your Honor, we would tender as substantive evidence the SIR guidelines, 7312.

THE COURT: You're moving them into evidence?

MR. NORTH: Yes, Your Honor.

MR. JOHNSON: Judge. We object. 803(18) does not permit the admission of these into evidence.

THE COURT: What's your response, Mr. North?

MR. NORTH: My response is, Your Honor, and I know the Court hasn't seen the brief yet, they're not being offered for the truth of the matter asserted, they're being offered to show the general notice and knowledge in the medical community, and therefore are not hearsay.

THE COURT: All right. I'm not going to admit it at

this point. I'll be happy to hear you further on that issue.

MR. NORTH: Thank you, Your Honor.

THE COURT: Cross-examination?

MR. JOHNSON: Yes, sir.

C R O S S - E X A M I N A T I O N

BY MR. JOHNSON:

Q Good morning, sir.

A Good morning.

Q You indicated you are charging $350 per hour for your time?

A Yes.

Q And are you able to tell us how much you have charged Bard for all of your work in the filter litigation?

A Well, I can update you as to the most recent billing, which encompassed a period of over a year for many different cases, and that was this past year, and that was a total for medical records, chart review, image review, and multiple other patients, total of $39,212.

Q Well, sir, you've been doing this work for Bard for many, many years, haven't you?

A To the best of my memory, since approximately 2010.

Q And are you able to tell us what the total amount of compensation you've earned since 2010 to the present?

A No, Counselor. I'd have to actually go back and check those records. I don't have that total amount memorized, but

I think I gave you at least an estimate of what the recent billing has been.

Q All right. So you know that this litigation involves the Bard G2 filter?

A Yes.

Q We're here to talk about Bard, not other filters. Do you know that?

A Yes, I do.

Q And are you aware that there has never, ever been a determination that the Bard G2 filter is safe or effective?

A Well, I'm not aware of that. What I can say --

Q Sir, yes or no?

A Could you just repeat the question, please.

Q Sure. Are you aware that there has never been a determination by the FDA or any source that the Bard G2 filter is safe and effective?

MR. NORTH: Objection. Outside the scope of direct.

THE COURT: Overruled.

And, Doctor, answer yes or no if you can. If you cannot, just tell Mr. Johnson you cannot answer it yes or no.

THE WITNESS: Yes. Thank you.

I'd have to say I cannot answer that, and I can elaborate if you wish.

MR. JOHNSON: Okay.

Greg, can you locate Exhibit 6842 and just publish it

11:45:24 to the witness.

And if you would go to page 2 of that exhibit.

BY MR. JOHNSON:

Q Sir, you're familiar with this document? That's the

11:45:39 recent and current guidelines regarding filters.

A Yes.

Q And do you see about three quarters of the way down where it says, "Although retrievable filters are often placed as permanent devices, no long-term safety and efficacy of these

11:45:59 devices as a class" --

THE COURT: I think you -- I think you misread that, Mr. Johnson. Why don't you try it again.

MR. JOHNSON: Oh, I'm sorry.

BY MR. JOHNSON:

11:46:07 Q "The long-term safety and efficacy of these devices as a class have not been established."

A I would agree with your reading of that sentence.

Q So there has never been a determination of efficacy and safety for the Bard G2 filter. Agreed?

11:46:34 A No, sir, only because it's my understanding as in the U.S. all filter devices must be accepted. There is a presentation of data for safety, efficacy --

MR. JOHNSON: Judge, this is going outside of the scope of my question. I object.

11:46:59 THE WITNESS: -- for the USFDA --

MR. JOHNSON: Sir --

THE COURT: Hold on just a minute, sir.

Overruled.

Next question.

MR. JOHNSON: Yes, sir.

BY MR. JOHNSON:

Q With regard to the SIR guidelines that you were a part of, that article itself is not a Level 1 article, is it?

A That article is a guideline by consensus committee so that in the sense that you're using, usually the term Level 1 evidence applies to clinical trials. So that would be a committee consensus document.

Q All right. Not a Level 1 study; correct?

A When -- when using the term in the sense that I believe you're meaning, yes.

Q All right. And reference was made to the Ferris article, which is a part of the article you were the lead author on. Do you remember that?

A I do.

Q The Ferris article is not a Level 1 study either, is it?

A The Ferris article is a center or multi-center type, so would not be considered Level 1 because, to the best of my knowledge, it did not start as a randomized clinical trial.

Q All right. So the short answer to my question is it is not a Level 1 study.

11:48:36 A Correct.
Q And the Ferris article did not study any retrievable filter, did it?
A That's true.
11:48:46 Q That is, it studied old technology compared to the G2 filter, for example.
A Well, it studied permanent inferior vena cava filters, that's correct. I would not myself consider permanent inferior vena cava filters to be old because they're still in
11:49:04 clinical use.
Q All right.
And with regard to all of the medical literature that your committee looked at with respect to table 1 and table 2, none of those articles involved Level 1 studies, did they?
11:49:25 A I would have -- actually have to check back to see whether there were any citations in the multitude of references that were Level 1 evidence. But I think I can say this: That many, many of the citations in that article, that's correct, were not, strictly speaking, Level 1.
11:49:47 Q All right.
And with regard to your work with that committee that published that article, did Bard provide you or your committee members with any internal information?
A No, they did not.
11:50:02 Q And with regard to all of the literature that you've

reviewed as an expert in this case, have you seen any indication that Bard has provided any authors with any internal information?

A I do not personally know of internal or proprietary information that was provided to authors. I can only speak for myself personally.

Q With regard to the complication rates that are found in table 1 of your article, can we agree that complications are highly dependent upon and influenced by patient selection?

A No, I don't think I could completely agree with that statement.

Q Would you agree that the complication rates are highly dependent upon patient selection?

A No, I don't believe I could agree completely with that statement, only because of the fact that patient selection is one factor, and the rate of complications depends, in fairness, on a variety of factors: The device, the scenario of the inferior vena cava placement, and others.

Q Okay. So it also depends on the particular device used; correct?

A It would.

Q All right.

With regard to the other trackable events that you mentioned, can we agree that the data in that table represents reported outcomes from various publications and not the SIR

11:51:44 standard for complications?
A The article does represent the literature at the time in 2001 which was reported in medical publications, yes.
Q But it does not represent the SIR, the Society of
11:52:05 Interventional Radiology, standard for complications. You would agree with that?
A No, I wouldn't, sir, only because the SIR official publication as of the year of 2001 was the guidelines for percutaneous filter placement.
11:52:28 Q What about as of 2016? Would you agree that the trackable events are not the SIR standards for complications?
A As of 2016, again, in fairness, the events and trackable events would be those reported in the most recent SIR guidelines from the committee, which, as you know, was
11:52:57 updated.
Q All right.
MR. JOHNSON: Greg, would you pull up Exhibit 6842, page 13.
BY MR. JOHNSON:
11:53:06 Q Let's read the language under table 2, the other trackable events. Let's read that together, okay?
A Yes.
Q All right.
It says, "The data in the table represents reported
11:53:23 outcomes from various publications."

Did I read it correctly so far?

A Yes.

Q And here's the ending: "And not the SIR standard for complications."

Did I read that correctly?

A Yes, you did.

Q Okay. So this is not the SIR standard for complications. Agreed?

A I have to answer that question as a relative no because, by way of explanation, the SIR guidelines and the publications by the SIR were intended, as I had described earlier, to be educational, informative, and helpful for those working with IVC filters.

The goal was not to create a specific, rigid, definitive threshold; it was to help practitioners.

And so in the sense of your question to me I would have to say that the guidelines are just that, they're a series of guidelines.

Q All right. And these guidelines did not imply that the rates in the ranges referenced were fine, acceptable, or okay. Do you agree with that?

A Well, I can only say that the ranges referenced were those what we had found, what were in the medical literature, what we as physicians in the field experienced, and what our colleagues experienced. And so in that regard, we relied on

11:55:13 published data and we relied on our own day-to-day practical experience with patients.

Q Tell you what, let's see what you had to say about that in August of 2014 at page 524 of your deposition.

11:55:28 MR. JOHNSON: May I publish it, Your Honor?

THE COURT: To the witness.

MR. JOHNSON: Yes.

THE COURT: Just to the witness.

Oh, you mean generally?

11:55:39 MR. JOHNSON: Yes.

THE COURT: Oh, it's a video?

MR. JOHNSON: It is.

THE COURT: You may.

(The following video testimony was played:)

11:55:47 THE WITNESS: "And certainly I can say that in the quality improvement guidelines for IVC filter placement through the SIR, for which I was the first author, we did not imply that rates in that range are fine or acceptable or okay. We simply said that those were trackable events and

11:56:09 that responsible individuals should look at any adverse event, trigger a review, and do a quality assurance monitoring to make sure that they understand some of the root causes behind such a serious problem."

BY MR. JOHNSON:

11:56:29 Q Do you remember giving that answer?

11:56:31 A I do.
Q Okay. And would you agree with me that the SIR guidelines do not create safety thresholds for filters that relate to embolization, tilt, perforation, fracture, and the inability 11:56:49 to remove the filter?
A I can certainly say that the guidelines have attempted and I think in a very reasonable way have documented what our total considered experience was in this field.
As I mentioned on the video, our intent was to be 11:57:15 informative, instructive, and to offer these as a set of guidelines for those working with vena cava filters. And the guidelines are what they are.
Q All right. Let's go back to your deposition given on September 24 of 2014 at page 770.
11:57:32 MR. JOHNSON: With the Court's permission, I'd like to play that video.
THE COURT: You may.
(The following video testimony was played:)
QUESTION: "Just so we're clear, that exhibit and the 11:57:44 committee that you're a part of did not create safety thresholds with respect to the filters study that relate to perforation, fracture, migration, tilt, or the inability to remove the filter. Is that correct or not correct?"
ANSWER: "Yes, that's fair."

11:58:13 BY MR. JOHNSON:

Q Do you recall that answer to that question?

A I do in the context of the question which was asked of me.

Q All right. And would you agree with me that the SIR

11:58:24 guidelines are not intended as an instruction manual for filter manufacturers like Bard?

A They were not an information for users manual or an instruction manual. I think that that's clear. They were a set of guidelines drawn up by the SIR in a committee to those

11:58:50 working with filter devices --

Q They're not -- I'm sorry.

A -- so in answer to your question, that's correct, they were not an instruction manual.

Q They were not to be used by manufacturers like Bard;

11:59:05 correct?

A Well, I can't offer an opinion on that. The SIR guidelines are widely available online and in print. It's not for me to say who should or should not use them. And certainly by way of education or to be informative in the

11:59:22 field, anyone could read them.

Q Let's see what you had to say back in July --

THE COURT: Mr. Johnson, we'll do that after lunch. We've reached the 1 o'clock -- I'm sorry, the noon hour.

Ladies and gentlemen, we will break now and resume at

11:59:36 1 o'clock.

11:59:37 (The jury exited the courtroom.)

THE COURT: Please be seated.

Counsel, I understand that we don't have the redactions on the exhibits yet that you all have been working on. I understand defendants have identified some and are waiting for plaintiffs.

12:00:14 Just an update on where that is, please.

MS. MATARAZZO: Yes, Your Honor.

We went back and forth on the first round of redactions and we have a couple of sticking points that I wasn't able to work out or had time to work out with Mr. North yesterday. And then we provided also some redactions on Sunday night for some of the exhibits we knew were going to be an issue yesterday and we haven't heard back on those yet. So we're working it out.

12:00:26 12:00:44 I do have a list of six -- sorry, five exhibits that we don't have any objections on and they can just go in as-is. And I can either tell you those now or --

THE COURT: No, I don't think you need to tell me those now. I just want to make sure that we're staying on this. Because what we don't want to do is have this come up on Wednesday when we're about to close and have to deal with those issues. So if you could try to work it out, say, by tomorrow morning. That way, if there's something for me to rule on, we'll know.

12:00:56 12:01:11

12:01:14 MS. MATARAZZO: Yes, Your Honor. That's what we're planning to do.

THE COURT: Okay.

And for your information, this morning -- well, I
12:01:24 haven't allocated any time in the deposition. But short of that, plaintiff has used 33 minutes and the defense has used two hours and seven minutes. Subject to some reallocation in the deposition, I presume.

All right. See you at 1 o'clock.

(Recess taken at 12:02.)

(End of a.m. session transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 27th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter